AN OPEN CLINICAL STUDY ON "SOOLI KANAM" (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG KANA NEI

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CERTIFICATE

This is to certify that the dissertation entitled **"AN OPEN CLINICAL STUDY ON SOOLI KANAM" (CHILDHOOD BRONCHIAL ASTHMA)** is a bonafide work done by **Dr. D. JEEVITHA,** Government Siddha Medical College, Arumbakkam Chennai – 600 106 in partial fulfillment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2016 – 2019.

Name & Signature of the Guide

Name & Signature of the Head of Department

Name & Signature of the Dean/ Principal

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CONTENTS

INTRODUCTION

Siddha system of medicine is one of the pristine system of medicine complied by Siddhars, who lived a spiritual life in the southern region of India. Siddhars were the embodiment of spiritual wisdom, which they served the people not only to cure disease but also prevent disease and in turn to increase the life span of human beings. The word Siddhi means Endless Knowledge.

For one to live long with a healthy body, the 3 fold afflictions of vatham, pitham, kabam must be kept under control and in right proportion. When these 3 powers (Vali,Azhal,Ayyam) deviates from their natural state due to various causes the disease manifest. The five primordial elements produce Mukkutram.

Vali -Wind + Space

Pitham -Fire

Kabam -Earth + Water

The 3 powers / humor can be brought to their normal state by taking proper food on the basics of 6 tastes

Kuzhanthai Maruthuvam is one among glorious branch of siddha system which deals with Medical care of Infant, Children, Adolescent and also have hidden an enormous treasure for healthy society.

Here " Sooli kanam" is specifically taken for the Dissertation, as it probably correlates with childhood Asthma, which is a Respiratory disease encountered by a large population of children today and limits their daily activities.

In Balavagadam, the disease are categorized by two factors

- ✓ Aga Karana Noigal
- ✓ Pura Karana Noigal

"Ayyam koodir rendraal

Arivaiyar thuyar thannal"

The Above siddha verse quoted by Ayyodhidhasar, means the SOOLI KANAM (Bronchial asthma) occurs due to derangement in Kaba factor.

In Siddha system, according to Balavaagadam, Sooli kanam is compared with Bronchial asthma. Sooli kanam is one among the 24 types of Kanam mentioned in Balavaagadam but generally Bronchial asthma in Adult is compared with Iraippu noi.

Asthma is the most common chronic condition of childhood. Asthma is a Diffuse obstructive lung disease or chronic inflammatory disorder of airway due to inflammation of airway, increased mucus production, contraction of the Bronchial smooth muscle with hyperactivity of the airway to a variety of stimuli.

The prevalence and severity of Childhood asthma have increased substantially in recent years. Asthma tends to affect about 10% children globally. Recent data have shown that Asthma continues to affect 6 million school aged children with approximately half of these children experiencing asthma attack each year.

In India the mean prevalence was found to be 2.74%. Childhood asthma among children 13-14 years of age was lower than the younger children 6-7 years of age.

In Tamil Nadu at the age of 6-12 years the prevalence ranges from 18%

The major determinants of childhood asthma ae still unknown. Familial/ Genetic role for etiology is the most important factors. More over Rapid urbanization & common environmental triggers such as Air pollution, Allergies, Dust, Weather changes, Pets & dander, Mites are the most important predisposing factors for childhood asthma. Children are more susceptible to Respiratory disorder due to various factors like Poor immunity, Low lung recoil & weak Respiratory muscle.

Despite the fact that pediatric Asthma has become an important public health problem. It is one of the leading causes for Emergency care requirement & cause for considerable morbidity, disability and occasional mortality at all age. If Asthma is not treated properly it may lead to impoverished quality of life, repeated attacks which may be life threatening, poor growth & limitation of physical activity.

As children are the future of tomorrow, they must get rid of major socio-economic disease Bronchial Asthma & as a doctor we have responsibility for this. By using modern treatment like Nebulizer & inhaler provides temporary relief only, but in case of siddha system of medicine we can provide safe treatment without any side effect & cost-effective manner.

The Ghee based medicine which easily crosses the Blood brain barrier, as well as easy absorption in children so I prefer Ghee based medicines as my drug of choice. so here I choose KANA NEI a Lipid Based nutritive medicine to enhance immune, safe and efficient for the management of sooli Kanam (childhood bronchial asthma) as my dissertation topic.

AIM & OBJECTIVE

AIM:

The aim of the study is select the cases of **SOOLI KANAM** (Childhood Bronchial asthma) patients to administrate them with the trial drugs as per the line treatment and analysis both clinically and experimentally to prove the safety and efficacy of **"KANA NEI"** for the treatment of **SOOLI KANAM** (Childhood Bronchial asthma)

OBJECTIVES:

PRIMARY OBJECTIVE:

To study the therapeutic efficacy of the medicine **"KANA NEI"** in the treatment of **SOOLI KANAM** (Childhood Bronchial asthma)

SECONDARY OBJECTIVE:

The main objective of the present study is to create the knowledge about the siddha system and to highlight the efficacy of siddha drugs among people.

To explore the etiology, clinical features, diagnosis and investigation of **Sooli kanam** through various siddha literature.

To collect and review the idea mentioned in the primordial siddha literature about the disease **Sooli kanam.**

To make the comparative study of the siddha and modern aspects of the disease.

To study the pre – clinical analytical standardization and safety study in the experimental formulation of the **Kana nei.**

To evaluate the pharmacological study of the trial drug.

To evaluate the parents and children who were affected by the disease and how to stabilize their health through natural way like pranayamam, diet modification and personal hygiene.

To conduct the clinical trial to find out the efficacy of **Kana Nei.**

To have a detailed analysis of the disease **Sooli Kanam (Childhood Bronchial asthma)** through efficacy of the drug.

REVIEW OF LITERATURE

SIDDHA ASPECT

இயல்:

கணம் என்பது கர்ப்பச்சூடு எனக் கூறுவர். மாந்தத்தின் தொடர் நோயே கணமாகும். இது குழவிக்கு, மாந்த நோய் ஏற்பட்டு முழுவதும் குணமாகாமல் உடலில் இருந்தே முற்றி வரும். குழந்தைகள் பாலும் குடித்து சோறும் உண்ணும் பருவத்தில் உண்டாகும் நோயாகும். இது குழந்தைகளது மூன்றாமாண்டு முதல் ஏழாமாண்டு வரை துன்பத்தைக் கொடுக்கும் நோயாகும்.

நோய் வரும் வழி:

குழந்தை மருத்துவம் (பால வாகடம்) நூல் கணம் தோன்றுவதற்கான வழிகளை பின்வருமாறு கூறுகிறது.

“ஐயது கூடிற் றென்றால் அரிவையர் துயரந் தன்னால்

செய்யாற் புனலருத்திச் செறிசல் தோடந் தன்னால்

பையர வல்கு லாளும் பசியுட நிருந்த தாலும்

துய்யதோர் குழவி கட்குக் கனங்களுந் தோன்று மன்றோ”.

-குழந்தை மருத்துவம்

பொருள்:

1. ஐயமானது தன்னளவின் இருந்து கூடுவதாலும்
2. அரிவையர்க்கு (அரிவையர் என்பது பெண்களின் பருவங்களின் ஒன்றாகும்)
3. பல்வேறு வகைப்பட்ட நீரினை பருகுவதால் உண்டாகும் சலதோடத்தாலும்.
4. பசியுடன் இருக்கும் தாயின் பாலை உண்பதாலும் குழந்தைகளுக்கு கணநோய் தோன்றும்.

2) பிறநூல்களில் கூறப்பட்டுள்ள நோய்வரும் வழி:

கும்பமுனி பாலவாகடம் என்னும் ஏட்டில் கணத்தின் நோய் வரும் வழி பற்றி பின்வருமாறு கூறுகிறது.

"தரணிதனிலேயுறு சேயருடலுதனிலெ வரு கணைரோக வரலாறு கேள்
கனவுபெறு கெற்பமில் ரெணமது சூடினால் போகமது மிகு சூடினால்
விரவினுடனே பல தோசமதினாலினி தாயினுட பால் வேவினால்
விள்ளு பல விசமதால் தீயினுட காங்கையாய் இளவெயிலு
கொள்ளலாலும்
உரயுமாகராமது குரையுமதினாலினி உண்ணு பால் பேதமதினால்
உறமாகவே கடும் சூடுடனே உண்ணலால் புளித்த வகை
உண்ணலாலும்
புரைமேவும் அதிக பெரும் காரவகை தின்பதால் அத்தியது சூடு மிஞ்சி
புகழுரிய மாமிசம் கருகியது ரெணமே வற்றியதுவே யெழும்பும்"

-கும்பமுனி பாலவாகடம் பாடல்எண்-451 (ப.எண்:113)

கர்ப்பம் தரித்திருக்கும் சமயத்தில் புண் ஏற்படுவதலும், உணவு மிகுதியாக உட்கொள்வதாலும், தாய்க்கு ஏற்படும் தோசங்களாலும், தாய்பால் இறுகி கடினப்பட்டு கொள்வதாலும், தாயிக்கு பால் விடங்கள் ஏற்படுவதாலும், உடல் சூட்டினாலும், வெயிலில் திரிவதாலும், உணவு குறைவாக உட்கொள்வதாலும், உட்கொள்ளும் பாலில் ஏற்படும் பேதத்தினாலும், மிகு சூடான உணவை உட்கொள்வதாலும் புளித்த உணவு வகைகளை உண்ணலாலும், காரவகை உணவுகளை மிகுதியாக கொள்வதாலும், கர்ப்பையின் சூடு மிகுதியாகி கர்ப்பத்தில் உள்ள மகவின் உடல் மெலிந்து கணம் தோன்றும்.

3)"சரபேந்திர வைத்திய முறைகள்" கர்ப்பிணி பாலரோக சிகிச்சை பின்வருமாறு கூறுகிறது.

"தோன்றுமய்ய பதார்த்தந் தோயப்பகை

யூன்று தாகம் பசிமிகுந் துற்றிடில்

ஏன்ற துன்பமெல்லாம் வந்து சூழ்தலால்

ஆன்ற சேய்க்குக் கணங்களுமாகுமே".

-சரபேந்திர வைத்திய முறைகள் கர்ப்பிணி பாலரோக சிகிச்சை (ப.எண்: 57)

பொருள்:

மிகுதியாகக் கபத்தைத் விருத்தி செய்யக்கூடிய பதார்த்தங்களை சாப்பிடுவதினாலுன் பசியும் அதிகமாக இருக்கையில் தண்ணீர் அருந்துவதினாலும் பற்பல கணரோகங்கள் குழந்தைகளுக்கு உண்டாகும்.

நோய் தோன்றும் வயது:

கணம் தோன்றும் வயது பற்றி பல்வேறு கருத்துகள் உள்ளன. கணம் குழந்தைகள் பாலும் குடித்து சோறும் உண்ணும் பருவத்தில் வரும் நோயாகும். இது குழந்தையின் மூன்றாமாண்டு முதல் ஏழாமாண்டு வரை வரும் நோய் என்பதை,

"என்னவே கணா மூன்று வருடந் தொட்டே

ஏழாண்டு மட்டுக்கு மிருக்குங்காலம்"

-பாலவாகடம்.

என்னும் செய்யுள் வரிகளால் அறியலாம்.

4)"தன்வந்திரி வைத்தியம்" என்னும் நூலில் பின்வருமாறு கூறப்படுகிறது.

"சீரிய தொன்மை செய்த தீவினை தந்தையாகப்

பாரிலிப் பிறப்பிற் செய்த பாவமே தாயாகப்

பேரிய சயக் குமரன் விறந்திலா கிறமத்தப்பே

காரிய செவிலித் தாயாய் கணம் பெற வளரும் நாளில்"

- **தன்வந்திரி வைத்தியம்**

பொருள்:

முற்பிறவியில் செய்த தீவினைகள் தந்தையாகவும் இப்பிறவியில் செய்த தீவினைகள் தாயாகவும் கொண்டு குமாரனாகிய கணம் தோன்றுகிறது.

5)திருவள்ளுவ நாயனார் இயற்றிய நவரத்தின சிந்தாமணி-800 என்னும் நூலில் பின்வருமாறு கூறப்படுகிறது.

"பாரான கெற்பவெட்டை மீரும் பக்குவத்தில்

வேரான் விந்து வெளி பட்டு யோளி விழுந்த தென்றாற்

காரான் பிண்டங் கனலிலடி பட்டுக் காந்தியினாற்

கூராய் கனசுர மெய்து மென்றேயான் கூறினேமே".

பொருள்:

கெற்பவெட்டை மீறியிருக்கும் நேரத்தில் கருவுற்றிரிக்கும் தாயுடன் தந்தை சேர்வதால் கருவானது (பிண்டமானது) கனலில் அடிபட்டு கணம் வருகிறது.

இதை தவிர,

6) பரராச சேகரம் என்னும் நூலில் பாலரோக நிதான படலத்தில் கணம் குழந்தைகளின் 12 வயது வரையிலும் காணும் நோய் என கூறுகிறது.

அதாவது

"என்ற தோர் கணை கடாமுமிப்படி யெழுந்து பொங்கி
நின்ற பேர் பதினெட்டு தானிறைந்திரு மாண்டின் மேலாய்க்
கன்றிய பாலர் மெய்யிற் பன்னிரண்டாண்டு காறும்
நின்றிடு மென்று முண்ணாணிகழ்த்தினன் முனிவனன்றே".

- பரராச சேகரம் (பாலரோக நிதானம்)

பாலவாகடம் நூலில் கீழ்காணுமாறு கூறப்படுகிறது.

"மலமுஞ் சலமு மிகத் தீய்ந்து மார்பிலதிக சுரங்காயும்
மலமும் வயிறு மிக வெரியும் வளமாய் தலையு மிக மயக்கும்
சலமும் வரள் தீ தான் குறையும் சண்டாளம் போலுட் சுரமாம்
தலமே பன்னிரண்டாண்டு மட்டும் தனதாய் வருங் குணமிதுவே".

- **பாலவாகடம்**

எனவே, கணமானது குழந்தை பிறந்தது முதல் 12 ஆண்டு வரை தோன்றும் நோய் எனவும் கொள்ளலாம்.

கர்ப்பச் சூடு: (3 முதல் 7 வயது வரை)

"தொகையான் கணங்கள் எல்லாம் கர்ப்பச்சூடு".

-அயோத்திதாசர் பாலவாகடம்.

கர்ப்பச்சூடு என்பதில் சூடு என்பது அழல் தாதுவை குறிப்பதாகும். அகத்தியர் வல்லாதி நாடி நூலில் கருவை காப்பதில் அழல் தாதுவின் முக்கியத்துவத்தைப் பற்றி கீழ்கண்டவாறு கூறப்படுகிறது .

“பாண்மை என்ற விந்தங்கே ஊறும் போது

பாயுமப்பா வன்னியோடு வாயுந் தானே”

-அகத்தியர் வல்லாதி நாடி நூல்

விந்து சுரோணிதத்தோடு சேர்த்து கருவுறுதலுக்கு துணை புரிவது வாயு(வாதம்) ஆகும். அவ்வாறு உற்பத்தியான் கருவை காத்து வளர செய்வது அழல் தாதுவாகும்.

“வன்னியும் வாயுவு மாயிருந் சுக்கிலம்”

- **திருமந்திரம்**

நோய் ஏற்பட காரணங்கள்:

அழல் தாதுவும் வளிதாதுவும் சுக்கிலத்துடன் சேர்ந்தே இருக்கும் என திருமந்திரம் நூலில் கூறப்படுகிறது.

இவ்விரு நூல்களின் கூற்றுபடி சுக்கிலத்துடன் அழல் தாது உள்ளது என அறியலாம். இவ்வாறு சுக்கிலத்துடன் கூடிய அழல் தாது தன்னளவில் மிகுதிபடுவதால் சுக்கிலத்துடன் விகற்பம் ஏற்பட்டு கருவின் அழல் தாது மாறுபடுகிறது. இதனால் கருவிற்கு சூடு அதிகமாகிறது. இதனையே “கர்ப்பச்சூடு” எனக் கொள்ளலாம்.

மாந்தத்தின் தொடர் நோயே கணமாகும்:

- மாந்த நோய் ஏற்பட்டு முழுவதும் குணமாகாமல் உடலில் இருந்தே முற்றி வரும்.
- மாந்தம் என்பது உருவ நிலையில் உடல் நிலையில் மந்தம், அதாவது தாயின் உணவு பழக்கங்களால் குற்றங்கள் கேடடையும் போது குழந்தைகளுக்கு தோன்றும் கோளாறுகள் மாந்த நோய் ஆகும்.
- மாந்தம் தொடந்து நிலைப்பதால் உணவின் சாரம் உடற்கட்டுகளுக்கு சேர்வதில் தடைகள் ஏற்படுகிறது.
- சாரம் செந்நீராக மாறும் தன்மை பாதிக்கப்படுகிறது.
- மற்ற உடற்கட்டுகள் போடணிக்கப்படிவதில் பாதிப்பு
- உடற்கட்டுகளின் வன்மை குறைகிறது.
- கணத்தின் குறிகுணங்கள் தோன்றுகிறது.

வயதினை பொறுத்து:

கணம் தோன்றும் வயதுப்பற்றி பின்வரும் வரிகளில் அறியலாம்,

“என்னவே கணமூன்று வருடந் தொட்டே

ஏழாண்டு மட்டுக்கு மிருக்குங்காலம்”

- **பாலவாகடம்**

என்ற பாடலினால் மூன்று ஆண்டு முதல் ஏழு ஆண்டு வரை வரும் நோய் என்பதை அறியலாம்

கணத்தின் வகைகள்:

பல நூல்களில் பலவகைகளில் கணம் வகைப்படுத்தப்பட்டு இருக்கிறது

1)பாலவாகடம் நூலில் 24 வகையாக கூறப்படுகிறது

“கணங்கட்பேர் விரித்தறைக் கேள்நண் றாகக்

கனவாத கணம்பித்த கணங் குளிர்ந்த

மணமான சேத்மகணம் பிள்ளை கட்கு

மாந்தகணம் அதிற்பிரிவு ஐந்தாம் இப்பால்

துணமாநீர்க் கணம்பிரளிக் கணமு நல்ல

சூலிகணஞ் சுழிகண மகா கணந்தான்

குணமான ஊதுகணம் வரட்கணந்தான்

கொதிப்புகணம் வீக்ககணம் இன்னங் கேளே

கேளே நீ பிறக்கணமும் அந்த கன்தன்

கணமும்மந் தாரகணம் எரிக ணந்தான்

முளேநீ ராமகணம் ஆமகண மெத்த

முக்குகணம் மூலகணம் பேரா மத்தின்

வாளேசிங் கியோடிரத்த கணமாம் எல்லாம்

வருத்துரைத்த திருபஃது நாங்கு மாகக்

கோளேது இவைதானே மருத்து நூலின்

குறிப்பறிந்தார்க் கல்லாமல் மற்றோர்க் கேதே”

-பாலவாகடம்.

1. வளி கணம்
2. அழல் கணம்
3. ஐய கணம்
4. மாந்த கணம்
5. நீர்க் கணம்
6. பிரளிக் கணம்
7. சூலி கணம்
8. சுழி கணம்
9. மகா கணம்
10. ஊது கணம்
11. வரள் கணம்
12. கொதிப்பு கணம்
13. வீக்கக் கணம்
14. பிறக் கணம்
15. அந்தகக் கணம்
16. மந்தார கணம்
17. எரி கணம்
18. நீராம கணம்
19. ஆம கணம்
20. முக்கு கணம்
21. மூல கணம்
22. பேராம கணம்
23. ரத்த கணம்
24. சிங்கி மாந்த கணம்

2) ஆத்ம ரட்சாமிர்தம் எனும் வைத்திய சார சங்கிரம் என்னும் நூலில் பின்வருமாறு கூறப்படுகிறது.

“பாரப்பா கணவகுப்பு பதினெட்டாகும்

பாடினார் வாதகணம் பித்தகணமோடு

நேரப்பா சேத்மகணம் மாந்தகணமின்னம்

நீர்க்கணஞ் சூலைக்கணம் பிரளிகணந்தான்

சாரப்பா ஊதுகணம் சுழிகணந்தான்

சார்வான மாகணமும் வரட்கணந்தான்

கூரப்பா கொதிப்புகணம் பிறக்கணந்தான்

குறிப்பறிவாயையைந்து கணமுமாமே”

-ஆத்மரட்சாமிர்தம்.

மாந்த முதிர்ந்து,

1) வாத கணம்
2) பித்த கணம்
3) சேத்ம கணம்
4) மாந்த கணம்
5) நீர்க் கணம்
6) சூலைக் கணம்
7) பிரளிக் கணம்
8) ஊது கணம்
9) சுழி கணம்
10) மா கணம்
11) வரட் கணம்
12) கொதிப்பு கணம்
13) பிறக் கணம்
14) வீக்க கணம்
15) ஆமக் கணம்
16) தேரைக் கணம்
17) முக்கு கணம்
18) மூலக் கணம்
19) போர்க் கணம்
20) இரத்தக் கணம்
21) விமாந்த கணம்
22) ஊது மாந்த கணம்
23) அந்தக் கணம்
24) மந்தார கணம்
25) எரி கணம்

என கணங்கள் 25 வகைப்படும்

3) கும்பமுனி பாலவாகடம் எனும் நூல் கணத்தை 18 வகையாக கூறுகிறது.

“மாது கனிவோடினி கேளும் ரொன்பதில் பேரு வகையானதி நீ

மருவு சுரமோடினி தூங்குகணை ரெத்தமும் வறட்சையோடு வெப்பு கணையும்

போதமோடு வீங்கலும் அனல்கணை மாந்தமும் மஞ்சளும் நீலமதுவும்

பொங்கிடும் சர்த்தியோடு ரத்தமும் மேகமுடனே வாலேந்திரன் வாலை சந்திரன்

மோதுமினி அத்தியின் சுரக்கனை மகேந்திர உள்ளுரொகம் பெயரிவைகள்

முறையாகவே யிவை வகைய தொன்று மேலதாய் ஈராறு வயது மட்டும்

கோதகலு பாலரை வாதையது செய்யும்மெ குணமோடவு சதங்கள்

கூறாகவேயினி மேலாலுரைக்கிறேன் ஒவ்வொன்றும் ஊன்றி அறியே"

-கும்பமுனி பாலவகடம் பாடல் எண்:452(ப.எண் :114)

அவைகள்:

1) சுரக்கணை
2) தூங்கு கணை
3) மூலரெத்தக் கணை
4) வறட்சைக் கணை
5) வெப்பு கணை
6) அனல் கணை
7) வீங்கு கணை
8) மாந்தக் கணை
9) மஞ்சள் கணை
10) நீலக் கணை
11) சத்திக் கணை
12) ரெத்தக் கணை
13) மேக க் கணை
14) அத்திச்சுர கணை
15) வலேந்திரக் கணை
16) வால சந்திர கணை
17) மகேந்திரக் கணை
18) உள்ளு ரோகக் கணை

4.பரராச சேகரம் எனும் நூலில் கணத்தின் வகைகள்-18 என்று கூறுகிறது

அதாவது,

"உரமெனுற கணைகண் முன்னேருரைத்தாவறுரைப்படக் கேண்மின்

"சுரமெனுற் கணையுமொன்று துங்குமக் கணையுமொன்று

நிரவிய மூல மிரத்த நீங்கரும் வரட்சி வெப்புக்

கருவுறு மனலன் வீங்கி கூடியதோர் மஞ்ச ணீலன்

நீலமாங் கணாய்யினேடு நின்றிடு வெளுப்பு மாகும்

சாலவே சத்தி மேலிந் தப்பிலா மாந்தா மேகம்

மேலதாம் வினைகள் போல மிருந்திடுற் கழிச்சல் காசம்

ஆலமாரிரும வெய்ப்பு மாவிவை பதினெட்டாமே”

-பரராசசேகரம்

1) வாத கணை
2) பித்த கணை
3) சுரக் கணை
4) அத்திசுர கணை
5) வரட் கணை
6) வாலசந்திர
7) மகேந்திர கணை
8) தூக்கு கணை
9) அனற் கணை
10) வீங்கு கணை
11) வெளுப்பு கணை
12) சத்தி கணை
13) இரத்த கணை
14) மூலக் கணை
15) கருங் கணை
16) மஞ்சட் கணை
17) நிலக் கணை
18) வெப்பு கணை

5.ஜீவரட்சாமிர்தம் எனும் நூல்-8 வகையாக் கூறுகிறது

1) சூலி கணம்
2) முக்கு கணம்
3) ஆம கணம்
4) தேரை கணம்
5) மகா கணம்
6) சுழி கணம்
7) கழி கணம்
8) வரள் கணம்

6)அயோத்திதாசர் பாலவாகடம் நூலில் 24 வகையாக கூறப்படுகிறது.

அவைகள்:

1) வளி கணம்
2) அழற் கணம்
3) ஐய கணம்
4) மாந்த கணம்
5) நீர்க் கணம்
13) வீக்க கணம்
14) பிறக் கணம்
15) அந்தக் கணம்
16) மந்தார கணம்
17) எரி கணம்

6) பிரளி கணம்
7) சூலி கணம்
8) சுழி கணம்
9) மகா கணம்
10) ஊது கணம்
11) வரள் கணம்
12) கொதிப்பு கணம்
18) நீராம கணம்
19) ஆம கணம்
20) முக்கு கணம்
21) மூல கணம்
22) பேராம கணம்
23) ரத்த கணம்
24) சிங்கி மாந்த கணம்

7) சரபேந்திர வைத்திய முறைகள் கர்ப்பிணி பாலரோகசிகிச்சை என்னும் நூல் கூறும் வகைகள்

1) நீர்க் கணம்
2) வரட் கணம்
3) எரி கணம்
4) சுழி கணம்
5) மூல கணம்
6) முக்கு கணம்
7) விக் கணம்
8) ஆம கணம்
9) நீர்க் கணம்
10) வரட் கணம்
11) எரி கணம்
12) சுழி கணம்
13) மூல கணம்
14) முக்கு கணம்
15) விக் கணம்
16) ஆம கணம்

என கணத்தின் வகைகள் கூறப்பட்டுள்ளன

8) தன்வந்திரி வைத்தியம் சயரோக நிதானம் என்னும் நூலின் படி 8 வகையாக கூறப்படுகிறது.

அவைகள்:

1) வால சயம்
2) வீர சயம்
3) தருண சயம்
4) கணிக சயம்

9)ஆவியளிக்கும் அமுத முறைச் சுருக்கம் எனும் நூல் 23 வகையாக கூறுகிறது.

அவைகள்:

1) வாத கணம்
2) பித்த கணம்
3) சிலேத்தும கணம்
4) மாந்த கணம்
5) நீர்க் கணம்
6) பிரளி கணம்
7) சூலை கணம்
8) சுழி கணம்
9) மகா கணம்
10) ஊது கணம்
11) வறட்சி கணம்
12) கொதிப்பு கணம்
13) வீக்க கணம்
14) பிறக் கணம்
15) ஆமக் கணம்
16) வரள் கணம்
17) முக்கு கணம்
18) போர்க் கணம்
19) இரத்தக் கணம்
20) நச்சு மாந்த கணம்
21) ஊது மாந்த கணம்
22) எரி கணம்
23) மந்தார கணம்

“தானான் தேரை கணம் முக்கு கணந்தான்

தனியான மூல கணம் போர் கணந்தான்

ஊணான் ரத்த கணம் விடா மாந்த கணமும்

ஊது மாந்தக் கணமாம் மாந்த கணந்தானும்

கோனான மந்தார கணமுந் தானும்

கூரான எரிகணமா மிருபத்து மூன்றும்

பானான கணங்கள் பன்னிரண்டு பகர்ந்ததாமே”

-ஆவியளிக்கும் அமுத முறைச் சுருக்கம்

10)பிள்ளைப்பிணி வாகடம் எனும் நூல் 8 வகையாக கூறுகிறது.

1) வரள் கணம்
2) மூல கணம்
3) சீத கணம்
4) இதய கணம்
5) மகா கணம்
6) மலக் கணக்
7) குண்டலிய கணம்
8) நீர் கணம்

என கணத்தின் வகைகள் கூறப்பட்டுள்ளன

முக்குற்ற வேறுபாடு:

உணவாதி செயல், அக, புற காரணங்களால் ஏற்படும் சுக்கில சுரோணித தோடங்களின் வேறுபாடுகளாலும் விந்துவுடன் உட்செல்லும் பிராணன், வெளியிலிருந்து காக்கும் அபானன், கருவை வளர்க்கும் உதானன் ஆகிய வாயுக்கள் பாதிப்படைந்து அழல் குற்றம் மிகுதிபட்டு கர்ப்பச்சூடு உண்டாகிறது. மிகுதிபட்ட அழலானது கபத்தின் இருப்பிடமான மார்பு பகுதியை பற்றி கொண்டு கபத்தை வளர்ச்சி பெற செய்து கணத்தின் குறிகுணங்களை உண்டாக்குகிறது.

சூலி கணம்:

குழந்தைகளுக்கு உண்டாகும் கணையின் ஒரு வகை சூலி கணம் ஆகும்.

சூலி கணம் -விளக்கம்: (பாலவாகடம்)

கர்ப்பத்திலேற்பட்ட கணச்சூட்டினால் குழந்தைகளுக்குண்டாம் ஓர் மேல்மூச்சு இதற்கு கர்ப்பக்கணை நோய் என்னும் பெயர்.

சூலி கணம் – குறிகுணங்கள் :

“உண்டாஞ் சூலி கணங்கேளாய்

உற்ற சுவாச மேலேலு ம்பிபித்

தண்டா இருமல் மிக உண்டாம்

தொண்டை நாவு மேவந்து

சோரும் பொருமி வயிற்றுப்பும்

வண்டார் முலையுங் குடியாது

வகையாய் முகமும் நாறுமன்றே”

-பாலவாகடம் , ப.எண்.294

பொருள்:

- மேல் மூச்சு உண்டாதல்
- இருமல் அதிகமாக ஏற்படுதல்
- நெஞ்சு, வாய், தொண்டை நாக்கு வெந்து புண்ணாதல்
- வயிற்றுப் பொருமல் உண்டாதல்
- தாய்ப்பால் உண்ண சிரமம்
- முகத்தில் நாற்றமடிக்கும் என்று பாலவாகடம் நூலில் கூறப்பட்டுள்ளது.

நெஞ்சு வாய் தொண்டை நாவு

நேருறு வெந்து புண்ணாய்

துஞ்சல்தன் முலையுண்ணாது

சுவாசமோ டிரும லுண்டாம்

தஞ்சமாய் வயிறு பொருமித்

தாய்முலை யுண்டோட் டாது

கஞ்சலை முகமும் நாறும்

கணசூலிக் கணமி தாமே”

“உடலது வெளுத்து நாவும்

உதடுக ளெயிறும் வெந்து

திடமுடன் முலையுண்ணாது

சிவந்துநீ ரெரிந்து வீழும்

அடர்ம லம்பிசின் போலா

தல்லது நுரைத்து வீழ்தல்

படர்சுரம் வயிற்று லுண்டாம்

பகர்கெர்ப்ப கணம தானே”

-பிள்ளைபிணி மருத்துவம்,பாகம்-2, ப,எண்-334

பொருள்:

- நெஞ்சு, தொண்டை, நா புண்ணாதல்
- தாய்ப்பால் உண்ணாமை
- சுவாசம், இருமல்
- வயிறு பொருமல்
- முகம் நாறுதல்
- உடல் வெளுத்தல்
- உதடு வயிறு புண்ணாதல்
- நீர் எரிச்சல்
- மலச்சிக்கல்
- வயிற்றில் சுரம் காய்தல் என்று பிள்ளை பிணி மருத்துவம் நூலில் கூறப்பட்டுள்ளது.

சூலிகணரோகம்

மேல்மூச்சு, இருமல், நெஞ்சு நாவும் நாபியும் புண் போலிருத்தல், பாலுண்ணாமை, முகநாற்றம் என்னும் இக்குணங்களை உண்டாக்கும் என்று ஜீவரட்சாமிர்தம் சிறப்பாயிரம் நூலில் சூலிகணரோகம் என்ற தலைப்பில் கூறப்பட்டுள்ளது.

-ஜீவரட்சாமிர்தம் ப.எண்:288

நோய் கணிப்பு (DIAGNOSIS):

சித்த மருத்துவம் நோய்கணிப்பு:

- பிணியறி முறைமை
- உயிர் தாதுக்கள் (முக்குற்றம்)
- உடல் தாதுக்கள் (ஏழு உடற்கட்டுக்கள்)
- பருவகாலங்கள்
- ஐவகை தேர்வு
- எண்வகைத் தேர்வு
- நீர்க்குறி
- நெய்க்குறி
- நாடி
- மேற்கூறிய காரணிகளின் மாறுபாடுகளை ஒன்றுடன் ஒன்று ஒப்பிட்டு நோய் கணிக்கப்படுகிறது.

பிணியறிமுறைமை:

1. பொறியால் அறிதல்
2. புலனால் அறிதல்
3. வினாதல்

சூலிகணத்தில் நோயாளிக்கு காணும் குறிகுணம்:

1.பொறியால் அறிதல்:

மூக்கு - மூக்கு நீர்பாய்தல்
நா - கோழை நுரைதல்
கண் - சிலவேலை கண்சிவத்தல்
காது - இயல்பு
தோல் – சிலவேலை அரிப்பு தடிப்பு காணல்

2.புலனால் அறிதல்:

ஊறு - வெப்பம்
ஓசை - இயல்பு
ஒளி - இயல்பு

சுவை - இனிப்பு சுவை தெரிதல்

நாற்றம் - மூக்கில் சளி சவ்வு தடிப்புறுதல்

3.வினாதல் : (கேட்டறிதல்)

மருத்துவன் தன்னை நோக்கி வந்த பிணியுற்றவனைப் பற்றி அறிய வேண்டியவற்றை அறிந்தும், தன் பொறி புலங்களால் நோயாளியின் பொறி புலன் வழியாய் உணர்வதை நோயாளியினிடத்தே (அ) அவன் பெற்றோர் சுற்றத்தாரைக் கொண்டோ அவனது பெயர், வயது, திணை, குடும்ப வரலாறு, உணவு பழக்கவழக்கம், முந்தைய நோயின் வரலாறு, ஒவ்வாமை வரலாறு போன்றவற்றை அறிதல் ஆகும்.

உயிர்தாதுக்கள்:

1. **வாதம்:**

சூலிக்கணத்தில் காணப்படும் வாதத்தின் நிலை:

1.பிராணன் - பாதிப்பு (மூச்சுவிடல், வாங்கலில் சிரமம்)

2.அபானன் -பாதிப்பு(மலச்சிக்கல், உடல் வன்மை குறைதல்)

3.வியானன் - பாதிப்பு (உடல் குன்றுதல்)

4.சமானன - பாதிப்பு (பிற வாயுக்களை கட்டுப்படித்துவதில்

சிரமம்

5.உதானன் -பாதிப்பு (இருமல்,வாந்தி,மேல்மூச்சு, பேச்சொலி குறைதல் உடல் சோர்வு)

6.நாகன் - பாதிப்பு (படித்தல், விளையாடல் போன்ற

செயல்களை செய்ய சிரமம்)

7.கூர்மன் - இயல்பு

8.கிருகரன் - பாதிப்பு (வாயில் கோழை நுரைதல், இருமல், மூக்கு நீர் பாய்தல், பசியின்மை)

9.தேவதத்தன் - பாதிப்பு (ஸில வேளை மிகுந்த அசதி காணல்)

10.தனஞ்செயன்.

2.பித்தம்:

சூலிக்கணத்தில் பித்தத்தின் நிலை:

1.அனற்பித்தம் - பாதிப்பு (பசியின்மை, செரியாமை)

2.இரஞ்சகபித்தம் - பாதிப்பு (உடல் வெளுப்பு)

3.சாதகப்பித்தம் -பாதிப்பு (அன்றாட வேலைகளை செய்வதில் சிரமம்)

4.பிராசகம் – சில வேலை பாதிப்பு (தோலில் அரிப்பு)

5.ஆலோசகம் – இயல்பு

3.கபம்:

சூலிகணத்தின் கபத்தின் நிலை:

1.அவலம்பகம் - பாதிப்பு (மூச்சு விட சிரமம்)

2.கிலேதகம் - பாதிப்பு (செரியாமை)

3.போதகம் - இயல்பு

4.தற்பகம் - சில வேளை பாதிப்பு (கண் சிவத்தல்)

5.சந்திகம் - இயல்பு

உடற்கட்டுகள்:

சூலிகணத்தில் உடற்கட்டுகளின் நிலை:

1.சாரம் - பாதிப்பு (உடல் சோர்வு, உடல்குன்றல்)

2.செந்நீர் - பாதிப்பு (உடல் வெளுப்பு)

3.ஊண் - பாதிப்பு (உடல் இளைப்பு)

4.கொழுப்பு - இயல்பு

5.என்பு - இயல்பு

6.மூளை - இயல்பு

7.வெண்ணீர்/ சுரோணிதம்

பருவகாலங்கள்:

1.கார்காலம் - ஆவணி, புரட்டாசி (Aug, Sep)

2.கூதிர்காலம் - ஐப்பசி, கார்த்திகை (Oct, Nov)

3.முன்பனி - மார்கழி, தை (Dec, Jan)

4.பின்பனி - மாசி, பங்குனி (Feb, Mar)

5.இளவேனில் - சித்திரை, வைகாசி (Apr, May)

6.முதுவேனில் - ஆனி, ஆடி (Jun, July)

முக்குற்றங்களும் பருவகாலங்களும்:

வ.எண்	பருவகாலங்கள்	குற்றங்கள்	குற்றத்தின் நிலை
1	கார்காலம்	வாதம் பித்தம்	வேற்றுநிலை வளர்ச்சி தன்னிலை வளர்ச்சி
2	கூதிர்காலம்	வாதம் பித்தம்	தன்னிலை வள்ர்ச்சி வேற்றுநிலை வளர்ச்சி
3	முன்பனிகாலம்	பித்தம்	தன்னிலை வளர்ச்சி
4	பின்பனிகாலம்	கபம்	தன்னிலை வளர்ச்சி
5	இளவேனில்காலம்	கபம்	வேற்றுநிலை வளர்ச்சி
6	முதுவேனில்காலம்	வாதம்	தன்னிலை வளர்ச்சி

சூலிகணத்தில் பருவகாலங்கள்:

சூலிகணத்தில் பித்ததோடம் பாதிப்படைந்து தன்னிலை வளர்ச்சி அடைந்து பின்னர் வளிகுற்றம் வேற்றுநிலை வளர்ச்சி அடைந்து அதன்பின் கபமானது தன்னிலை வளர்ச்சி அடைந்து சூலிகணத்தின் குறிகுணங்கள் தோற்றிவிக்கின்றன.

எனவே கார்காலம் முதல் பின்பினி காலம் வரையுள்ள காலம் சூலிகணம் தோன்றுவதற்குரிய காலங்களாக்கும் (Sep to March)

ஐவகை நிலங்கள்:

1.குறிஞ்சி (மலையும் மலை சார்ந்த இடமும்)- சிலேத்துமம் தங்கும்

2.முல்லை (காடும் காடு சார்ந்த இடமும்) – வல்லை வாத நோய் உண்டாக்கும்.

3.மருதம் (வயலும் வயல் சார்ந்த இடமும்) – முத்தோட நோய்களை ஒழிக்கும்.

4.நெய்தல் (கடலும் கடல் சார்ந்த இடமும்) – வாத நோய் குடல் வாயு உண்டாக்கும்

5.பாலை (மணலும் மணல் சார்ந்த இடமும்) – முத்தோட நோய்களுக்கு இருப்பிடம்.

எண்வகைத் தேர்வு:

“நாடி பரிசம் நாநிறம் மொழிவிழி

மலம் மூத்திரமிவை மருத்துவராயுதம்”

சூலிகணத்தின் எண்வகை தேர்வின் நிலை:

1.நா – மஞ்சள் (அ) பச்சை மஞ்சள் நிறம்

2.நிறம் – தோல், கண், நா, நகம் வெளுத்தல்

3.மொழி – குரல் ஒலி தாழ்தன்

4.விழி – சிலவேளை கண் சிவத்தல், வெளுப்பு, கண் அரிப்பு காணல்.

5.மலம் – மலக்கட்டு

6.மூத்திரம் – வெண்மை கலந்த மஞ்சள் நிறத்துடன் நுரை காணல்

7.ஸ்பரிசம் – சிலவேளை சுரம் இருந்தால் மிகு வெப்பமாகவும் சிலவேளை தட்பமாகவும், வியர்வையும் காணும்.

8.நாடி – வாத கபம், பித்த கபம், வாத பித்தம்.

நீர்க்குறி:

"அருந்து மாறிரதமும் அவிரோதமதாய்

அக்கல் அலர்தல் அகாலவூன் தவிர்ந்தழற்

குற்றளவருத்தி உறங்கி வைகறை

ஆடிக்கலசத் தாவியே காதுபெய்

தொரு முகூர்த்தக் கலைக்குட்படு நீரின்

நீர்க்குறி நெய்க்குறி நிருமித்தல் கடனே"

விளக்கம்:

நீர்க்குறி பார்க்கும் முதல் நாள் இரவு நன்கு உணவு உண்ண வேண்டும். பின் விடியற்காலை படிகபாத்திரத்தில் நீரினை பிடித்து அதன் நீர்க்குறி மற்றும் நிறக்குறியினை கண்டறிதல் வேண்டும்.

"வந்த நீர் கரியெடை மணம் நுரை ஏஞ்சலென்

றைந்தியலுளவவை யரைகுது முறையே"

-நோய் நாடல் முதல் பாகம்

நீரில் நிறம் மணம் நுரை, எடை எஞ்சல் இவற்றை காண வேண்டும்.

நெய்க்குறி:

“நீர்க்குறி குரைத்த நிருமான நீரிற்

சிறக்க வெண்னெய்யோர் சிறுதுளி நடுவிடுத்

தென்னுறத் திறந்தவெளி யோகா தமைந்ததி

நின்றதிவலை பொம் நெறிவிழியறிவும்

சிறுநீரில் நல்லெண்ணெய் விட்டு பார்ப்பது”.

விளக்கம்:

கணநோயாளின் சிறுநீரை சோதனை வட்டிலில் ஊற்றி, சூரிய ஒளி மிகுந்த இடத்தில் நீரின் அலையில்லாத போது நல்லெண்ணெய்த்துளி விட்டு பார்ப்பது.

“அரவென நீண்டில் வாதம்

ஆழிபோற் பரவின் பித்தம்

முத்தொத்து நிற்கின் கபம்”

அரவு (பாம்பு) போல் பரவினால் வாத நீர் ஆழி (மோதிரம்) போல் பரவினால் பித்த நீர் முத்து போல் பரவினால் கப நீர் ஆகும்.

நாடி:

சூலிகணத்தில் சதக நாடி நடை:

வாத பித்த நாடி:

“பொருளான வாதத்தில் பித்தஞ் சேர்ந்து

பொருத்து குணங்களா முஷ்ணவாயு சத்தி

செரியாமை புளித்தேப்பம் பொருமல் நீரிற்

சிவப்பு மலம் பிடித்தலுருந் தாதுநட்டம்

கருவான தேகமதி லுளைச்சல் சோம்பல்”

வாத கப நாடி:

“பாங்கான வாதத்தில் சேத்தும நாடிப்

பரிசித்தால் திமிர்மேவு முளைச்சலாகும்

தீங்கான இருமலுடன் சந்தி தோடம்

வாங்காத ஈளைமந் தார காசம்

வலியுடனே புறவீச்சு உள்வீச்சு

ஓங்காணுஞ் சுரமுடனே சுவாசகாசம்

உண்டாக்கும் வெகுநோய்க்கு முறுதி தானே”

-சதக நாடி

மருத்துவம்:

“நோய் நாடி நோய் முதல் நாடி அது தணிக்கும்

வாய்நாடி வாய்ப்பச் செயல்”

“நோய்நாடல், நோய்முதனாடல்” இவ்விரண்டும் பிணியை அறிவதற்க்கு இன்றியமையாதது பற்றியும், அதன் பிறகுதான் மருந்தைக் குறிப்பிடல் வேண்டும்.

“உற்றான ளவும் பிணியளவுங் காலமும்

கற்றான் கருதிச் செயல்”

மருத்துவ வழிமுறை:

- ✓ தன்னிலை வளர்ச்சியடைந்த ஐயத்தையும், வாதத்தையும் சமப்படுத்த வேண்டும்.
- ✓ .தன்னிலை வளர்ச்சியடைந்த பித்ததை சமப்படுத்த வேண்டும்.
- ✓ வன்மை இழந்த உடற்கட்டுகளை வன்மை அடையச் செய்யும் மருந்தளிக்க வேண்டும்.

LINE OF TREATMENT:

1.Kaapu (prevention)

2.Neekam (Treatment)

3.Niraivu (Restoration)

1.Kaapu:

- Prevention is the main aim of siddha system. Siddhars have described general preventive measures and special measures.
- Especially in Balavaagadam, special preventive measures that are said for preventive of disease of the child starts from the time of conception in intra uterine life and also after delivery.
- The diet of pregnant women, her habits, specific medicine to be taken in each month of pregnancy, psychological condition and surroundings influence the prevention of disease in the expected child.

2.Neekam:

The aim of treatment is as follows:

- To bring the vitiated three dhoshas into normal equilibrium state.
- To treat the patients according to the symptoms by internal medicine – Kana nei.
- To Teach them simple breathing exercise which can be followed regularly at home.

3.Niraivu:

- Reassurance of disease recovery was given to all patients.
- All the patients were adviced to have a healthy life style that provides a disease free life.
- Anxiety and general fear about the disease was discouraged by educating the patients and their parents.
- All the patients were insisted for regular follow up for the assessment of prognosis which regained their confidence about disease recovery.

பத்தியம்: (DIET)

“பத்தியத்தினாலே பலனுண்டாம் மருந்து

பத்தியங்கள் போல் பலன் போகும்- பத்தியத்தில்

பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால்

பத்தியமே உத்தி யென்று பார்”

-தேரையர்

மருந்துண்ணும் காலங்களில் நோயாளியின் நோயின் தன்மை பொருத்து உணவு மற்றும் செயல்களில் ஆகும் ஆகா பத்தியங்கள் அறிவுருத்தப்படுகிறது.

உணவு:

ஆகும் பத்தியம்:

கணம் நோயாளிக்கு ஆகும் கறி விவரம்:

“கண்டு கொள்வார் கறிவகைக்கு விவரம் கேளு

கதலியுட காயாகும் முருங்கைப் பிஞ்சு

கண்டு சிறுகீரை நெல்லிக்காய் தானாகும்

தக்க துவரை அவரையுட பிஞ்சுமாகும்

பண்டு நெய் பால் கற்கண்டு தூதுளங்காய் ஆகும்

பரிவான் முயலுடும்பின் இறைச்சியாகும்

கொண்டுடன் வெள்ளாடு வெள்ளெலியும்

குலத்திலுள்ள விரால் மசிறியாகும்”

-மதலைநோய் தொகுதி-॥

விளக்கம்:

- வாழைக்காய், முருங்கைபிஞ்சு, நெல்லிக்காய், துவரை, அவரைப்பிஞ்சு,
- தூதுங்காய், நெய், பால், கற்கண்டு, முயல் இறைச்சி, உடும்பு இறைச்சி,
- வெள்ளெலி, விரால்மீன், மசிறி
- இவை கணம் நோயாளிக்கு ஆகும் உணவு பதார்த்தமாகும்.

ஆகா பத்தியம்:

- குளிர்ந்த நீர், குளிர்பாணங்கள், ஐஸ்கிரீம், இனிப்பு வகைகள்,
- எளிதில் செரிக்காத மாப்பண்டங்கள். பாகல்,
- அகத்திகீரை, குளிர்ச்சியான காய்கறிகள்,
- நோயாளிக்கு ஒவ்வாத பழவகைகள்.

நோய் தடுப்பு முறை மற்றும் மருத்துவம் அறிவுரை:

- நோயாளி தனக்கு ஒவ்வாத பொருட்களை கண்டறிந்து அதனை நீக்க வேண்டும்.
- சுகாரமற்ற உணவுவகைகள் மற்றும் நீரினை தவிர்க்கவும்.
- குளிர்காற்று, பனிகாற்றில் வெளியில் செல்வதை தவிர்க்கவும்.
- உணவினை இளஞ்சூட்டில் உண்ண வேண்டும்.
- இரவில் உணவை சீக்கரம் உண்டு சிறிதுநேரம் சென்ற பின்பு உறங்க செல்ல வேண்டும்.
- நோய் எதிர்ப்பு சக்தியை தரும் சத்துள்ள உணவுகளை உண்ண வேண்டும்.
- புரிந்து கொள்ளும் வயதிலுள்ள குழந்தைகளுக்கு பிராணாயாமம் போன்ற எளிய மூச்சு பயிற்சி முறைகளை கற்று தருதல் வேண்டும்.

MODERN ASPECT

CELLULAR DEVELOPMENT OF LUNG IN UTERO

At about 26 weeks of gestation, the lung reaches the stage of full maturity at which capable of supporting life the rest of the time spent in the utero from 26 weeks to term is for the development and subdivision of the respiratory bronchioles, the saccules and for the growth of the airways

POST- NATAL DEVELOPMENT:

At the time of birth there are very few true alveoli, and gaseous exchange take place through saccules or terminal airspaces. The alveoli start appearing after birth, first on peripheral saccules, then towards proximal respiratory bronchioles and terminal bronchioles. About 127 million alveoli are present at one year and about 280 million alveoli have developed by age of 8 years.

PECULARITIES OF RESPIRATORY TRACT IN CHILDREN:

Chest wall is thin, elastic yielding and the intrinsic muscles are weak. Short thorax with the ribs running more horizontally. Increase in antero-posterior diameter of the chest with limited respiration. Epiglottis is longer and projects backwards at a greater degree than in older children.

All these peculiarities tend to increase the risk of permanent deformity in the chest wall in the presence of recurrent or longstanding respiratory distress. By above 8 years the chest assumes conical shape since the antero-posterior diameter is less than the transverse diameter and the ribs are placed in a slightly downward direction.

ANATOMY & PHYSIOLOGY OF RESPIRATORY SYSTEM

Lungs are a pair of Respiratory organs situated in the thoracic cavity. Each lung innervates the corresponding pleural cavity. In young, the lungs are brown or grey in color. Gradually, they become mottled black because of the deposition of inhaled carbon particles. The right lung weights about 700g. It is about 50-100g heavier than the left lung.

The Respiratory system is a Biological system, consisting of specific organs and structures facilitate gas exchange in human.

For all air breathing vertebrates, respiration is handled by the lungs, but these are far from the only components of the respiratory system. In fact, the system is composed of the following biological structures:

1.Nose

2.Mouth

3.Pharynx

4.Larynx

5.Trachea

6.Bronchi and bronchioles

7.Lungs

8.The muscles of respiration

ANATOMICAL COMPONENTS

NOSE AND NASAL CAVITY:

The nose and the nasal cavity facilitate the main route of air entry. The nose is made out of bone, muscle, cartilage and skin, while the nasal cavity is more or less hollow space. The nose is typically credited as being the main external breathing apparatus.

The cavity is lined with mucus membranes and little hairs that can filter the air before it goes into the respiratory tract. The two cavities divided by a Septum. Anteriorly consist hyaline cartilage. The Roof is formed ethmoid bone. The floor is formed by roof of the mouth. The medial wall formed by the septum. The lateral wall formed by the maxilla.

RESPIRATORY FUNCTION OF THE NOSE:

Nose is the entry way to the respiratory tract a passage through the body which air uses for travel in order to reach the lungs. The following functions are given below

1.Warming:

Due to immense vascularity of the mucosa.

2.Filtering and cleaning:

This occurs due to hairs which trap larger particles.

3.Humidification:

As air travels over the moist mucosa, it becomes saturated with water vapour.

ORAL CAVITY:

The oral cavity, more commonly referred to as the mouth, is the only other external component that is part of the respiratory system. Normally breathing through nose is preferable to breathing through the mouth.

Not only does the mouth not possess the ability to warm and moisturize the air coming in but it also lacks the hairs and mucous membranes to filter out unwanted contaminants. On the plus side, the pathway leading from the mouth is shorter and the diameter is wider, which means that more ai can entry the body at the same speed.

PHARYNX:

The larynx is the part of the throat that is behind the mouth and nasal cavity and above the esophagus and the larynx. Length 12-14cm (extend from the base of the skull to the level of 6^{th} cervical vertebra)

- ✓ Superiorly consist of Base of the skull
- ✓ Inferiorly it continues with the esophagus
- ✓ Anteriorly formed by incomplete wall because of the nose, mouth and larynx opening.
- ✓ Posteriorly – areolar tissues and first 6 vertebra.

The pharynx is divided into three parts:

1) Nasopharynx

2) oropharynx

3) laryngopharynx

The nasopharynx is the upper region of the structure, which begins at the posterior of the nasal cavity and simply allows air to travel through it and reach the lower sections.

The oropharynx does something similar, except it is located at the posterior of the oral cavity. Once the air reaches the laryngopharynx, something called the epiglottis will divert it to the larynx

LARYNX:

The larynx or voice box extends from the root of the tongue. It lies in front of the laryngopharynx at the level of 3^{rd},4^{th}, 5^{th} and 6^{th} cervical vertebra. Until the puberty there is little difference in the size of the larynx between the sexes. The afore mentioned epiglottis is part of larynx, as are the thyroid cartilage, the cricoid cartilage and the vocal folds. The thyroid cartilage also goes by a more common name – the Adam's apple, although contrary to popular, belief it is present in both men and women. The functions of larynx are

- ✓ Production of sound
- ✓ Speech
- ✓ Protection of Lower respiratory tract- during swallowing the larynx moves upwards and hinged epiglottis closes over the larynx.

TRACHEA:

Below the larynx is the trachea, or the windpipe. The trachea is the major airway for the body and it is made up and held open by hard c- shaped rings of cartilage. The cartilage are open at the back (connected by trachealis muscle). The cartilage stiffens the trachea and prevents the pipe from collapsing in on itself. This hard cartilage can be felt in the front of the neck. The esophagus is behind the trachea.

The trachea is lined with mucous membranes. The mucus in the trachea traps any foreign particles that get paste the mucus and hairs in the nose. At the bifurcation of the trachea, there is the presence of a sensitive carina. Anything that touches the carina causes a cough reflex (for protection).

The function of trachea are

- ✓ Support and patency
- ✓ Mucociliary escalator
- ✓ Cough reflex
- ✓ Warming
- ✓ Humidifying
- ✓ Filtering

BRONCHI:

The lower end of the trachea splits the respiratory tract into two branches that are named the primary bronchi. These first run into each of the lungs before further branching off into smaller bronchi. These secondary bronchi continue carrying the air to the lobes of the lobes of the lungs, and then further split into tertiary bronchi.

The tertiary bronchi then split into even smaller sections that are spread out throughout the lungs called bronchioles. Each one of these bronchioles continues to split into even smaller parts called terminal bronchioles. The tiny bronchioles do not have any kind of cartilage and instead rely on muscles and elastin. The walls of the bronchi and bronchioles are also lined with muscle tissue, which can control the flow of air going into the lungs.

LUNGS:

The lungs are two organs located inside the thorax on the left and right sides. They are surrounded by a membrane that provides them with enough space to expand when they fill up with air. The left lung is smaller and has only two lobes while the right lung has three.

Inside the lungs resemble a sponge made of millions of small sacs that are named alveoli. These alveoli are found at the ends of terminal bronchioles and are surrounded by capillaries through which blood passes.

PLEURA AND PLEURAL CAVITY:

The inside of the thoracic cavities and the lung surface are covered with serous membranes, respectively the parietal pleura and the visceral pleura, which are in direct continuity at the hilum.

Depending on the subjacent structures, the parietal pleura can be subdivided into three portions: the mediastinal, costal and diaphragmatic pleurae. The shape of the lungs is determined by the shape of the pleural cavities. Because of the presence of pleural recesses, which form a kind of reserve space, the pleural cavity is larger than the lung volume.

The lungs are maintained in close opposition to the thoracic wall by a negative pressure between visceral and parietal pleurae. A thin film of extracellular fluid between the pleurae enables the lungs to move smoothly along the walls of the cavity during breathing.

MUSCLES OF RESPIRATION:

The last component of the respiratory system is a muscle structure known as the muscles of respiration. These muscles surround the lungs and allow the inhalation and exhalation of air. The main muscle in this system is known as the diaphragm, a thin sheet of muscle that constitutes the bottom of the thorax.

It pulls in air into the lungs by contracting several inches with each breath. In addition to the diaphragm, multiple intercostals muscles are located between the ribs and they also help compress and expand the lungs.

BLOOD SUPPLY:

The Human Lung has a dual blood supply.

The Tissue of the lung receive oxygenated blood via the bronchial circulation, a series of arteries that leave the aorta and a part of the systemic circulation. There are usually three arteries and they branch alongside the Bronchi and bronchioles.

On the right side there is one bronchial artery which arises from either the third posterior intercostal artery or from the upper left bronchial artery. On the left side there are two bronchial arteries both which arises from descending thoracic aorta.

The Blood volume of lungs is about 450 milli meter on average, about 9 percent of the total volume of the entire circulatory system.

In this process, venous blood in the body collects in the Right atrium and is pumped from the right ventricles through the pulmonary trunk and the pulmonary arteries into the left and right lungs.

The blood passes through small capillaries next to alveoli in the lungs, receives oxygen, and travels back to the heart. This is called the pulmonary circulation.

LYMPHATIC DRAINAGE:

Superficial vessels drain the peripheral lung tissue lying beneath the pulmonary pleura. The vessels pass round the borders of the lung and margins of the fissures to reach the hilum. Deep lymphatics drain the bronchial tree, the pulmonary vessels and the connective tissue septa. They run towards the hilum where they drain into the bronchopulmonary nodes.

NERVE SUPPLY:

The lungs are supplied by nerves of the autonomic nervous system. Input from the parasympathetic nervous system occur via the vagus nerve. These fibers are (i) motor to the bronchial muscles and on stimulation cause bronchospasm. (ii) secretomotor to the mucous glands of the bronchial tree and (iii) sensory. The sensory fibers are responsible for the cough reflex.

When stimulated by acetylcholine, this causes constriction of the smooth muscle lining the bronchus and bronchiole, increases the secretion from the glands

The lungs also have a sympathetic tone from the norepinephrine acting on the beta 2 receptors in the respiratory tract, which causes bronchodilation

The action of breathing takes place because of nerve signal sent by the respiratory center in the brainstem, along the phrenic nerve to the diaphragm.

RESPIRATION:

During normal quiet breathing, inspiration is the active process and expiration is the passive process. During inspiration, thoracic cage enlarges and lungs expand. During expiration, the thoracic cage decrease in size and attain the pre inspiratory position.

MUSCLES OF RESPIRATION:

The expansion of the chest during inspiration occurs partly voluntary and partly involuntary. The muscles of normal quiet breathing are the intercostal muscles and the diaphragm. During difficult breathing they are assisted by the muscles of the neck, shoulder and abdomen.

CYCLES OF RESPIRATION:

This occurs 12-15 times per minute and consists of three phases.

1) Inspiration

2) Expiration

3) Pause

INSPIRATION:

The capacity of the thoracic cavity is increased by simultaneous contraction of the inter costal muscles and the diaphragm. The parietal pleura move with the walls of thorax and the diaphragm. This reduces the pressure in the pleural cavity to the level considerably lower than the atmospheric pressure. The visual pleura follow the parietal pleura. During the process, the lungs are stretched; the pressure within the alveoli and the air passage reduced drawing air into the lungs in an attempt to equalize the atmospheric and alveolar air pressure.

The process of inspiration is active as it requires expenditure of energy for muscle contraction. The negative pressure created in the thoracic cavity aids venous return to the heart and is known as respiratory pump.

EXPIRATION:

Relaxation of inter costal muscles and the diaphragm results in the downward and inward movement of the rib cage and the elastic recoil of the lungs. As this occurs, the pressure of the gases inside the thorax exceeds the atmospheric pressure and therefore air is expelled from the respiratory tract. The lungs still contain some air and are prevented from complete collapse by the intact pleura. The process is passive as it does not require the expenditure of energy.

After expiration there is a pause, before the next cycle begins.

Physiology Variables Affects Respiration

ELASTICITY:

Loss of elasticity of the connective tissue in the lungs necessitates forced expiration and increased effort of inspiration.

COMPLIANCE:

The ability of lungs and thorax to expand or the expansibility of lungs and thorax is called the compliance. It is defined as the change in volume per unit change in the pressure.

AIR FLOW RESISTANCE:

When this is increased e.g. in broncho constriction, more respiratory effort is required to inflate the lungs.

PULMONARY FUNCTION TEST:

Pulmonary function tests are useful in assessing the functional status of the respiratory system both in physiological and pathological conditions. Pulmonary function tests are carried out mostly by using spirometer.

The air in lung is classified into two divisions:

I Lung volume

II Lung capacities

Lung volume:

Lung volumes are the volumes of air breathed by an individual during altered pattern of respiration. The lung volumes are dynamic and are four types

I. Tidal volume

II. Inspiratory reserve volume

III. Expiratory reserve volume

IV. Residual volume

Tidal Volume (TV):

The volume of air breathed in and out of lungs in a single normal quiet respiration is called tidal volume. Tidal volume signifies the normal depth of breathing. Normal value 500 ml.

Inspiratory Reserve Volume (IRV):

An additional amount of air that can be inspired forcefully after the end of normal inspiration beyond tidal volume is called the inspiratory reserve volume. Normal volume 3300 ml

Expiratory Reserve Volume (ERV):

The additional amount of air that can be expired out forcefully, after normal expiration is called the expiratory reserve volume. Normal volume 1000 ml

Residual Volume:

Normally, lungs cannot be emptied completely even by forceful expiration. Some amount of air always remains in the lungs even after the forced expiration. The amount of air remaining in the lungs even after forced expiration is called residual volume.

It is significant because of two reasons:

I. It helps to aerate the blood in between breathing and during expiration II. It maintains the contour of the lungs

Lung capacities:

Two or more lung volumes together are called lung capacities. Lung capacities are of four types:

I. Inspiratory capacity

II. Vital capacity

III. Functional residual capacity

IV. Total lung capacity

Inspiratory capacity (IC):

It is the maximum volume of air that is inspired from end expiratory position. Inspiratory capacity includes tidal volume and inspiratory reserve volume.

IC = TV + IRV=500+3300=3800ml

Vital capacity (VC):

It is the maximum amount of air that is expelled out forcefully after a maximal (deep) inspiration. Vital capacity includes inspiratory reserve volume, tidal volume and expiratory reserve volume.

VC= IRV+TV+ERV=3300+500+1000=4800ml

Functional residual capacity (FRV):

It is the volume of air remaining in the lungs after normal expiration. Functional residual capacity includes expiratory reserve volume and reserve volume.

FRV= ERV+RV=1000=+1200=2200ml

Total lung capacity (TLC):

Total lung capacity is the amount of air present in the lungs after a maximal inspiration. It includes all the volumes.

TLC=IRV+TV+ERV+RV=3300+500+1000+1200=6000

Alveolar Ventilation:

This is the volume of air that moves into and out of the alveoli per minute. It is the tidal volume minus the anatomical dead space, multiplied by the respiratory rate.

Alveolar ventilation = (TV-anatomical dead space) respiratory rate = (500-150) ml x 15 per minute = 5.25liters / minute.

Lungs function tests are carried out to determine respiratory function and are based on the parameters out lined above.

EXTERNAL RESPIRATION:

This is the exchange between alveoli and blood. Total area of gas exchange in the lungs is 70-80 square meters. CO2 diffuses from venous blood along the contraction gradient into the alveoli until equilibrium with alveolar air is reached. By the same process O2 diffuses from alveoli to the blood.

INTERNAL RESPIRATION:

This is the exchange of air between the tissue and blood. When there is difference in partial pressures, oxygen diffuses outward from the blood to extra cellular fluid then into the cell walls. The process involved is diffusion.

CONTROL OF RESPIRATION:

Control of respiration is normally involuntary. Voluntary control is exerted during activities such as speaking, singing but is over ridded if homeostasis of arterial PO2 and PCO2 is threatened i.e. if this is high arterial PCO2 or low arterial PO2.

RESPIRATORY CENTER:

The Respiratory centers are divided into three areas on the basics of their functions:

1. **The Medullary rhythmicity area in the medulla oblongata**
2. **The pneumotaxic area in the pons**
3. **The Apneustic area in the pons**

The function of Medullary rhythmicity area is to control the basic rhythm of respiration.it include two areas.

a.Inspiratory Medullary rhythmicity area – When its inspiratory neurons fire, a burst of impulse travels along the Phrenic and Intercostal nerves to excite the diaphragm and external intercostal muscles.

b.Expiratory Medullary rhymicity area – Its causes the contraction of the internal intercostal and abdominal muscles, which decreases the size of the thoracic cavity and causes forceful exhalation.

Pneumotaxic Area:

It transmits inhibitory impulse to the inspiratory area. The major effect of these nerve impulse is to help turn off the inspiratory area before the lungs become too full of air.

Apneustic Area:

This area sends stimulatory impulse to the inspiratory area that activate it and prolong inhalation. The result is a Long, deep, inhalation.

BRONCHIAL ASTHMA

DEFINITION:

Bronchial asthma is a common chronic inflammatory condition of the airways characterized by increased responsiveness of tracheobronchial tree to a variety of stimuli resulting in widespread narrowing of the air space. The term “asthma” in Greek means “ breathless ” or “ breathe with open mouth ”

PREVALANCE:

1. Around 0.5-2 percentage of the population suffers from asthma

2. 8.9 million children had been diagnosed with asthma in their life time, boys (14%) and girls (10%)

3. The international study on asthma and allergies in childhood (ISAAC) reported prevalence of breathing difficulty in 9 % of children in rural area of Tamil nadu.

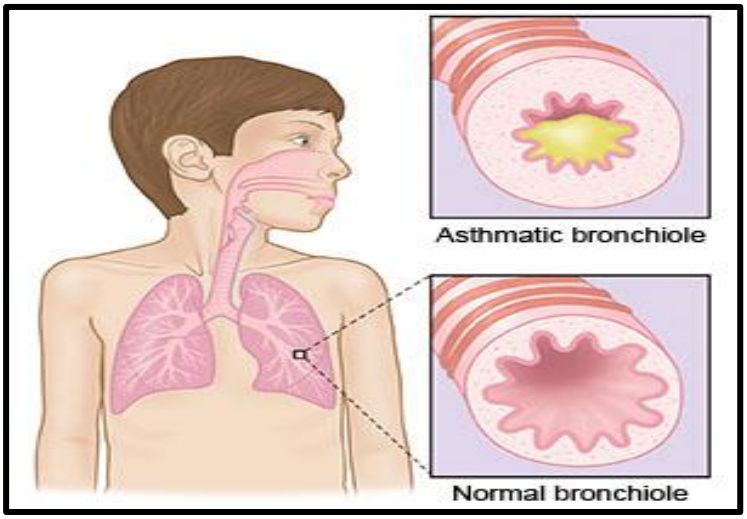
4. India has estimated 15 to 20 million asthmatics peoples

ETIOLOGY:

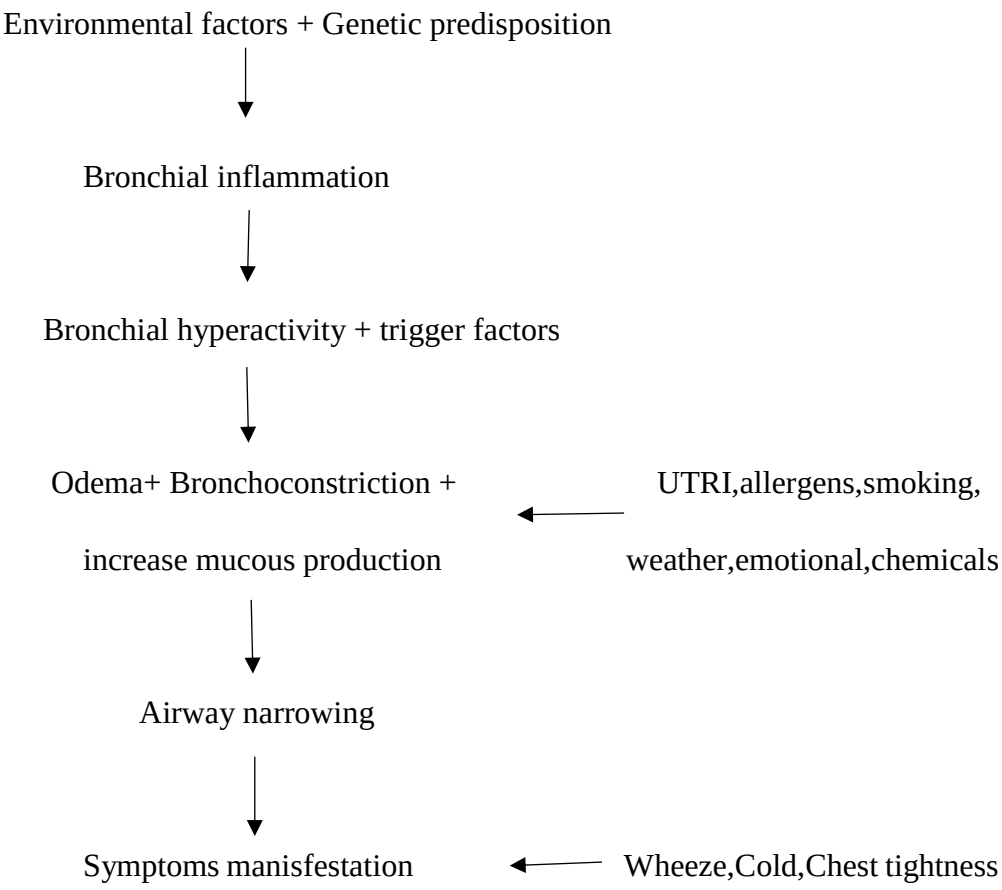
1. Allergens such as Food, Pollens, Dust, Mites and Pet dander.
2. Air pollutions and toxins.
3. Emotional stress and anxiety.
4. Weather, especially extreme changes in temperature.
5. Infections bacterial, viral fungal.

Genetic Predisposition:

Genetic factors play a contributing role in the Pathogenesis of asthma. Molecular genetic linkage studies indicate that the 'Atopic' gene locus is on chromosome 11 and the genes for cytokines that are important components in the pathogenesis of asthma are encoded in chromosome 5. The allergic cytokines are IL 3,4,5,9,13 and granulocyte macrophage colony stimulating factor. All these are linked to inheritance of an increased Ig E response and increased bronchial responsiveness.



PATHOPHYSIOLOGY OF ASTHMA:



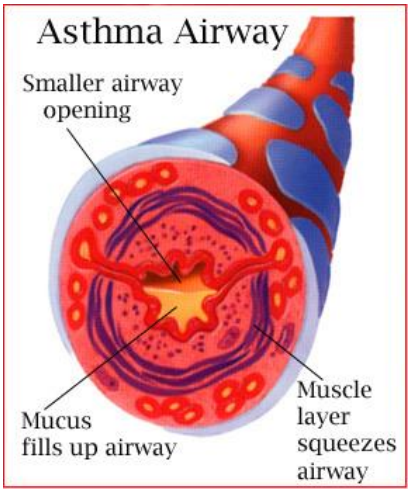
Airway obstruction (or airway narrowing), that is reversible (at least partially), either spontaneously or with treatment.

Airway inflammation

Airway hyper responsiveness to a variety of stimuli

Airway obstruction is responsible for the clinical manifestations of asthma such as wheezing, dyspnea, and cough.

Airway obstruction, which is determined by the diameter of the airway lumen, can be influenced by a number of factors, including edema of the bronchial wall, mucus production, airway smooth muscle contraction, and airway remodeling suggesting a rationale for early initiation of anti- inflammatory therapy.



1.**Airway inflammation:**

The airways of asthma patients are infiltrated by a number of different inflammatory cells, which then cause epithelial disruption and mucosal edema. An initial trigger in asthma may cause the release of inflammatory mediators from bronchial mast cells, macrophages and epithelial cells.

In addition to the release of cytokines by mast cells, T-cells, fibroblasts, endothelial cells and epithelial cells activate neutrophils, eosinophils and macrophages, which produce chronic allergic inflammation characteristic of asthma.

This process produces epithelial injury, abnormalities in neural mechanisms, increase in airway smooth muscle responsiveness, and airflow obstruction. Epithelial injury can lead to increased permeability and sensitivity to inhaled allergens, irritants, and inflammatory mediators.

In addition, transduction of fluids and reduced clearance of inflammatory substances and respiratory secretions occur with disruption of epithelium mucociliary mechanisms. The inflammatory process may chronically irritate the airway leading to chronic cough symptoms.

2.Airway hyperresponsiveness:

Airway hyperresponsiveness is an exaggerated bronchoconstrictor response to many physical, chemical and pharmacological agents e.g., allergens, environmental irritants, viral respiratory infections: cold air or exercise.

The level of airway hyperresponsiveness usually correlates with the clinical severity of asthma and with medication requirement. Atopy, the genetic predisposition for the development of an IgE mediated response to common aero allergens, is the strongest identifiable predisposing factor for developing asthma.

The stimuli that interact with airway responsiveness and incite acute episodes of asthma can be grouped into ten major categories – allergic, pharmacological, environmental, occupational, infections, and exercise – related and emotional stress, food and drink, smoking, heart burn.

Allergens:

An allergy with asthma is a common problem. Eighty percent of people with asthma have allergies to airborne substances such as tree, grass, and weed pollens, mold, animal dander, dust mites, and cockroach particles.

Allergic asthma is dependent on IgE response controlled by T and B lymphocytes and activated by the interaction of antigen with mast cells-bound IgE molecule.

Air pollutants:

Children with asthma who are exposed to maternal smoking have higher requirements for medication and more frequent emergency department visits. Other irritants such as wood smoke, household sprays, volatile organic compounds (e.g. polishes and cooking oils), and air pollutants may also exacerbate asthma.

Respiratory infections:

It is well established that viral respiratory infections can excertable asthma, particularly in children with asthma under the age of 10. Respiratory syncytial virus, rhinovirus, and influenza virus have been implicated, with rhinovirus being implicated in the majority of the exacerbation of asthma in children.

The role of infections as triggers also appears to be important but not common in adults. Respiratory virus may exacerbate asthma through different mechanism. One is that viral infections may cause epithelial damage and airway inflammation, both of which events may create asthma symptoms.

In addition, virus has been shown to potentiate the allergic response to allergens by increasing the release of inflammatory mediators and the cascade of inflammatory events characteristic of asthma.

Weather changes:

Adverse weather conditions such as freezing temperatures, high humidity, thunderstorms and episodes of acute pollution brought out by weather conditions have been associated with asthma exacerbations.

CLASSIFICATION OF ASTHMA:

Extrinsic asthma (atopic):

Nearly 90% of childhood asthma is extrinsic asthma which is allergic asthma. It is often associated with a personal and /or family history of allergic diseases such as rhinitis, urticaria and eczema. Positive wheal and flare skin reactions to intradermal injections of extracts of antigens and increased levels of IgE in serum.

Intrinsic asthma (non – atopic):

A Significant segment of asthmatic population will present with negative family or personal history of allergy, negative skin test. They have normal serum levels of IgE. Therefore cannot be classified on the basis of defined immunologic mechanisms, Many of these will develop a typical symptom complex upon contracting an upper respiratory illness, after several days the patient begins to develop paroxysms of wheezing and dyspnea that can last for days to months.

Asthma – three phenotypes

1.Transient Wheezer-onset <3yrs-then resolving

2.Persistent wheezer -<3yrs and persisting

3.Late onset-onset of wheeze between 3-6 yrs

CLINICAL MANIFESTATIONS:

Cardinal sign:

The presences of usually diffuse, polyphonic, bilateral and particularly expiratory wheeze is the cardinal sign of Asthma.

Most Common symptoms:

- ✓ Intermittent dry cough
- ✓ Expiratory wheeze
- ✓ Shortness of breath
- ✓ Chest tightness
- ✓ Intermittent non-focal chest pain
- ✓ Nocturnal cough
- ✓ Dyspnea
- ✓ Limitation of daily physical activity
- ✓ General fatigue

Associated symptoms:

- ✓ Allergic rhinitis
- ✓ Sneezing
- ✓ Itching
- ✓ Nasal Congestion
- ✓ Gastro esophageal reflux

Symptoms of severe persistent asthma:

Acute severe attacks on Asthma represent the progression of an attack of bronchospasm to the point where the patient is breathless at rest and has the signs of cardiac stress. They may be sudden onset, but more commonly build up over several hours or days.

The following are the symptoms of severe persistent asthma:

- ✓ Increasing breathlessness
- ✓ Difficulty in talking
- ✓ Anxiety to the stage of panic

- ✓ Feeble Breath sounds
- ✓ Absence of Wheeze (Silent chest)
- ✓ Profuse sweating, Restless ness
- ✓ Fatigue
- ✓ Respiratory distress
- ✓ Cardiac arrhythmias
- ✓ Pulsus paradoxus
- ✓ Cyanosis
- ✓ Visible overinflated chest (Barrel shaped)
- ✓ Difficulty in feeding
- ✓ Inability to talk in words or sentences

DIAGNOSIS:

The diagnosis of asthma is a clinical one. Hence detailed clinical history taking, physical examination and additional information regarding family history of Atopy, allergic exposures, circadian variations and seasonal exacerbations should be carefully considered.

DIFFERENTIAL DIAGNOSIS:

- ✓ Bronchiolitis
- ✓ Aspiration of foreign body
- ✓ Hypersensitivity pneumonitis

TRIAL DRUG REVIEW

PREPARATION AND PROPERITIES OF TRIAL DRUGS

KANA NEI (INTERNAL MEDICINE)

1.பருத்திவிதை பருப்பு:

BOTANICAL NAME: *Gossipium herbacium*

ENGLISH NAME: Cotton plant

FAMILY NAME: Malvaceae

SUVAI: Thuvarpu, Inipu

THANMAI: Veppam

PIRIVU: Kaarpu

பொது குணம்:

"பருத்தியிலை மொக்கிரண்டைப் பாலிலரைத் துண்ண

வருத்துகின்ற மேகமெல்லாம் மாறும் – பருத்த

விரத்தபித்தத் தோடு விரணவீக் கம்போம்

அரத்தவிதழ் மாதே யறை"

ACTIONS:

Expectorant, laxative

CHEMICAL CONSTITUENTS:

Flavonoids, Tannins, Saponin, terpenoids

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Expectorant, Antibacterial, Astringent

2.பொடுதலை காய்:

BOTANICAL NAME: *Phyla nodifera*

ENGLISH NAME: Purple lippia

FAMILY NAME: Verbenaceae

SUVAI: Kaipu, Thuvarpu

THANMAI: Veppam

PIRIVU: Kaarpu

பொது குணம்:

"பொடுதலையின் பேருரைத்தால் போராமப் போக்கும்

அடுதலைசெய் காசம் அடங்கும் – கடுகிவரு

பேதியொடு சூலைநோய் பேசரிய வெண்மேகம்

வாதமும்போ மெய்யுரக்கும் வாழ்த்து"

ACTIONS:

Expectorant, Demulcent, astringent

CHEMICAL CONSTITUENTS:

Nodifloridin A, Nodifloridin B, Lippiflorin A, Lippiflorin B

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Expectorant, Anti spasmodic, Astringent

3.கிராம்பு:

BOTANICAL NAME: *Syzygium aromaticum*

ENGLISH NAME: Clove

FAMILY NAME: Myrtaceae

SUVAI: Kaarpu

THANMAI: Veppam

PIRIVU: Kaarpu

பொது குணம்:

“பித்த மயக்கம் பேதியொடு வாந்தியும்போம்
சுத்தவிரத் தக்கடுப்புந் தோன்றுமோ- மெத்த
இலவங்கங் கொமண்டவருக் கேற் சுகமாகும்
மலமங்கே கட்டுமென வாழ்த்து.

சுக்கிலநட் டங்கர்ண சூர்வியங்க லாகஞ்சனந்தாட்
சிக்கல்விடாச் சர்வா சியப்பிணியு- மக்கிக்குட்
டங்கப் பூவோடு தரிபடருந் தோன்றிலில்
வங்கப்பூ வோடுரைந்து வா”

ACTIONS:

Anti-spasmodic, Carminative, Stomachic

CHEMICAL CONSTITUENTS:

Eugenol, Alpha- humulene, Beta caryophylleneoxide, Eugenyl acetate, Kaempferol, Quercetin.

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Carminative, Anti spasmodic, Anodyne

4.கிச்சிலி கிழங்கு:

BOTANICAL NAME: *Curcuma zedoaria*

ENGLISH NAME: Round white zedoary

FAMILY NAME: Zingiberaceae

SUVAI: Kaipu

THANMAI: Veppam

PIRIVU: Kaarpu

"நற் கிச்சிலியி ணொாண்கிழங் குங்கபமும்

பூட்டுமுட மும்புண்ணும் போம்"

ACTIONS:

Expectorant, Stimulant, Alterative, Carminative

CHEMICAL CONSTITUTIONS:

Borneol, Furanodiene, Furanodienone, camphene

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Expectorant, Carminative Anti allergic

5.சீரகம்:

BOTANICAL NAME: *Cuminum cyminum*

ENGLISH NAME: Cumin seeds

FAMILY NAME: Umbellifers

SUVAI: Kaarpu, Inippu

THANMAI: Thatpam

PIRIVU: Inippu

பொது குணம்:

“பித்தமெனு மந்திரியைப் பின்ன படுத்தியவன்

சத்துருவை யுந்துறந்து சாதித்து- மத்தனெனும்

ராசனையு மீவென்று நண்பைப் பலப்படுத்தி

போசனகு டாரிசெயும் போர்”

ACTIONS:

Carminative, Stimulant, Astringent

CHEMICAL CONSTITUTIONS:

Cuminosides A & B, Cumin aldehyde, Luteolin, Estrogole, Camphene

PHARMACOLOGICAL AVTIVITIES:

Anti-inflammatory, Bronchodilator, Antimicrobial

6.இலவம் பிசின்:

BOTANICAL NAME: *Bombax malabaricum*

ENGLISH NAME: capok tree or cotton tree

FAMILY NAME: Bombacaceae

SUVAI: Inipu, Thuvarppu

THANAMI: Thatpam

PIRIVU: Inippu

பொது குணம்:

“தந்துமே கஞ்சிறுநீர்த் தாரைவெப் பம்வாயு

வுந்தவரு பேதியிவை யோட்டுங்காண் – முந்திக்

கிளர்வள்ளை பாயும்வரிக் கொண்டை விழியாய்

வளர்முள் ளிலவு மரம்”

ACTIONS:

Astringent, styptic

CHEMICAL CONSTITUTIONS:

Kaempferol, Anthocyanin A, Anthocyanin B.

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Astringent, Anti pyretic, Antimicrobial

7.இலவங்கப்பட்டை:

BOTANICAL NAME: *Cinnamomum verum*

ENGLISH NAME: Bark of cinnamon

FAMILY NAME: Lauraceae

SUVAI: Kaarpu, Inippu

THANMAI: Thatpam

PIRIVU: Inippu

பொது குணம்:

“தாதுநட்டம் பேதி சருவவிஷம் ஆகியநோய்

பூதகிர கஞ்சிலந்திப் பூச்சிவிடஞ்- சாதிவிடம்

ஆட்டுமிரைப் போடிருமல் ஆகியநோய்க் கூட்டமற

ஓட்டுமில வங்கத் துரி”

ACTIONS:

Carminative, Stimulant

CHEMICAL CONSTITUTIONS:

Cinnamyl acetate, Eugenol, Cinnamaldehyde, Coumarin

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Carminative, Stimulant, Antimicrobial

8.சாதிக்காய்:

BOTANICAL NAME: *Myristica fragrans*

ENGLISH NAME: Nut meg

FAMILY NAME: Myristicaceae

SUVAI: Thuvarpu, Kaarpu

THANMAI: Veppam

PIRIVU: Kaarpu

பொது குணம்:

“தாது நட்டம் பேதி சருவாசி யஞ்சிர நோய்

ஓதுசுவா சங்காசம் உட்கிரணி- வேதோ

டிலக்காய் வரும்பிணிபோம் ஏற்றமயல் பித்தங்

குலக்கா யருந்துவர்க்குக் கூறு”

ACTIONS:

Stimulant, Carminative, Tonic

CHEMICAL CONSTITUTUIONS:

Eugenol, Isoeugenol, Methyl eugenol, Myristicin, Elemicin, Trimyristin.

PHARMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Carminative, Antibacterial, Astringent

9. காய்ச்சுக்கட்டி:

BOTANICAL NAME: *Catechu lozenges*

FAMILY NAME: Fabaceae

SUVAI: Thuvarppu

THANMAI: Thatpam

PIRIVU: Inippu

ACTIONS:

Styptic, carminative

CHEMICAL CONSTITUTIONS:

Catechin, Quercetin, Vanillic acid, Ferulic acid

PHARAMACOLOGICAL ACTIVITIES:

Anti-inflammatory, Antibacterial, Astringent, Antioxidant

10. பசு நெய் :

SUVAI: Inippu

THANMAI: Thatpam

PIRIVU: Inippu

பொது குணம்:

“தாகமுழ லைசுட்கம் வாந்தி பித்தம் வாயுபிர

மேகம் வயிற்றெரிவு விக்கலழல் – மாகாசங்

குன்மம் வறட்சி குடற்புரட்ட லஸ்திசுட்கஞ்

சொன்மூலம் போக்குநிறைத் துப்பு.”

ACTIONS ON THE DOSHAS:

Tridoshaic – balance Vatha, Pitha Kapha

ACTIONS:

Anti-fungal, Anti-oxidant, Anti-aging, Anti-bacterial, Anti-viral

CHEMICAL CONSTITUENTS:

Cow Ghee’s is abadunt in saturate fatty acids. It contains Approximately 8% saturated fatty acid which make it easily digestible. The digestible co- efficient or the rate absorption is 96% which is better than any other animal or vegetable fat.

It contains Triglyceride, diglycerides, monoglyceride, phospholipids contain beta carotene 600 IU and vitamin E which are known as Anti-oxidant.

MEDICINAL QUALITIES:

- ✓ It is cooling, tasty, tonic, appetizer
- ✓ It increases our capacity to digest food but also our capacity to absorb and assimilate it.
- ✓ It Increase intelligence, refines the intellect and improve the memory.
- ✓ It directly nourishes our immune system, as well as our life force and all of our tissues.
- ✓ It can stimulate secretion of stomach acid and thus helping in the digestive process.
- ✓ It increases the absorbability of Vitamin and minerals and thus help to improve overall health.
- ✓ It Balances all Agni (Digestive fires)
- ✓ Ghee increase the strength, luster and beauty of the body.

STANDARD OPERATING PROCEDURES OF KANA NEI:

SOURCE OF TRIAL MEDICINE:

The raw drug for the preparation of Kana nei will be purchased from a well reputed country shop and the purchased drugs will be authenticated by the competent authority (Medicinal Botany dept, GSMC, Chennai). After that the raw drugs will be purified separately then the trial drugs will be prepared in Gunapadam Laboratory of Government Siddha Medical college, Chennai-106

RAW DRUGS IDENTIFICATION AND AUTHENTICATION:

These ingredients were identified and were authenticated by Medicinal Botanist at GSMC, Arumbakkam, Chennai-600106.

INGREDIENTS OF KANA NEI:

1. PARUTHIVITHAI PARUPPU *(Gossipium herbacium)* - 21gm
2. PODUTHALAI KAAI *(Phyla nodifera)* - 21gm
3. KIRAMBU *(Syzygium aromaticum)* - 21gm
4. KICHILI KIZHANGU *(Curcuma zedoaria)* - 21gm
5. SEERAGAM *(Cuminum cyminum)* - 21gm
6. ELAVAMPISIN *(Bombax malabaricum)* - 21gm
7. ELAVANGAPATTAI *(Cinnamomum verum)* - 21gm
8. JAATHI KAAI *(Myristica fragrans)* - 21gm
9. KAAICHUKATTI *(Catechu lozenges)* - 21gm
10. COW GHEE - 350 ml

METHODS OF PURIFICATION:

Raw drugs are purified a mentioned in sikicharatna deepam sarakku suthi muraigal.

PARUTHIVITHAI PARUPPU:

Dried in sun shade and fried

PODUTHALAI KAAI:

Dried in sun shade

KIRAMBU:

Dried in sun shade and fried

KICHILLI KIZHANGU:

Dried

SEERAGAM:

Dried in sun shade and fried

ELAVAM PISIN:

Dried in sun shade and powdered

ELAVANGAPATTAI:

Dried in sun shade and fried

JAATHIKAAI:

Remove the outer cover, cut into small pieces and dried in sun shade

KAAICHUKATTI:

Dried in sun shade and powdered

COW GHEE:

melt and then used.

PREPARATION OF DRUG:

The above mentioned 9 raw drugs are purified and mildly fried separately made it into fine powder. Then the fine powder is mixed into ghee and the mixture is heated upto 2-3 boils and mixed well.

DOSE:

3 to 5 years - 1gm Twice a day

6 to 12 years - 2gm Twice a day

DURATION:

21 Days

REFERENCE:

Anuboga vaithiya kunabodhini

Kuzhanthaigal Avushatham

Dr. Vasudevan

Page no: 115.

KANA NEI

பருத்திவிதை பருப்பு

பொடுதலை காய்

கிராம்பு

கோரைக்கிழங்கு

சீரகம்

இலவம் பிசின்

இலவங்கப் பட்டை

சாதிக்காய்

காய்ச்சுக்கட்டி

பசு நெய்

கண நெய்

PRECLINICAL SAFETY STUDIES FOR KANA NEI

- Biochemical analysis
- Phytochemical analysis
- Physicochemical analysis
- TLC analysis & HPTLC analysis
- Specific pathogen
- Sterility test
- Heavy metal analysis
- Analysis of pesticides organochlorine, organophosphorus and pyrethroida
- Aflotoxins
- Aute Toxicity study
- Repeated oral toxicity study 28 days
- Pharmacological Activity

BIOCHEMICAL ANALYSIS:

III. Bio Chemical analysis of trial medicine Kana Nei for Soolikanam (Childhood bronchial asthma)

Preparation of sodium carbonate extract

2 gm of Kana nei sample is mixed with 5gm of sodium carbonate and taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes,cooled and then filtered. The filtrate is called sodium carbonate extract.

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
Test for Acid Radicals			
1A	**Test for sulphate:** 2ml of the above prepared extract is taken in a test tube.to this add 2ml of 4 % Ammonium oxalate solution.	Absence of white precipitate	Absent
B	2ml of extract is added with 2ml of dilute Hydrochloric acid until the effervescence ceases off.Then 2ml Barium chloride solution is added.	Absence of white precipitate	Absent
2	**Test for chloride:** 2ml of extract is added with dilute Nitric acid till the effervescence ceases.Then 2ml of silver nitrate solution is added.	presence of white precipitate	present

3	**Test for phosphate:** 2 ml of the extract is treated with 2 ml of Ammonium molybdate solution and 2 ml of concentrated nitric acid	Absence of Yellow precipitate	Absent
4	**Test for carbonate:** 2 ml of the extract is treated with 2 ml of Magnesium sulphate solution.	Absence of white precipitate	Absent
5	**Test for sulphide:** 1 gm of the substance is treated with 2 ml of concentrated Hydrochloric acid.	Absence of Rotten egg smelling	Absent
6	**Test for Fluoride and oxalate:** 2ml of extract is added with dilute Acetic acid and 2 ml of Calcium chloride solution and heated.	Absence of white precipitate	Absent
7	**Test for Borate:** 2 pinches of the substance is made into paste by using Sulphuric acid and alcohol (95%) and introduced into the blue flame.	Absence of Green tinged flame	Absent

TEST FOR BASIC RADICALS			
8	**Test for lead:** 2 ml of the extract is added with 2 ml of Potassium iodide solution.	Absence of yellow precipitate.	Absent

9	**Test for copper:** One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the nonluminous part of the flame.	Absence of Bluish green colored flame	Absent
10	**Test for aluminium:** To the 2 ml of extract Sodium hydroxide solution is added in drops in excess.	Absence of white precipitate	Absent
11	**Test for iron:** To the 2 ml of extract 2ml of Ammonium thiocyanate solution and 2ml of concentrated Nitric acid is added.	Presence of Blood red colour	Present
12	**Test for zinc:** To the 2 ml of extract Sodium hydroxide solution is added in drops in excess.	Absence of green tinged flame	Absent
13	**Test for calcium:** To the 2 ml of extract Ammonium oxalate solution solution is added	Presence of white precipitate	Present

14	**Test for magnesium:** To the 2 ml of extract Sodium hydroxide solution is added in drops in excess	Absence of white precipitate	Absent
15	**Test for ammonium:** To the 2 ml of extract few ml of Nessler‟s reagent and excess of Sodium hydroxide solution are added	Absence of white precipitate	Absent
16	**Test for sodium:** 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame	Absence of white precipitate	Absent
17	**Test for mercury:** 2 ml of extract is treated with 2ml of Sodium hydroxide solution.	Absence of Yellow precipitate	Absent
18	**Test for arsenic:** 2 ml of extract is treated with 2ml of Silver nitrate solution.	Absence of white precipitate	Absent
19	**Test for starch:** 2 ml of extracts treated with weak iodine solution.	Presence of white precipitate	Present
20	**Test for reducing sugar** 5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and	Presence of white precipitate	Present

	added 10 drops of the extract and again boiled for 2minutes.The colour changes are noted.		
21	**Test for alkaloids:** 2 ml of the extract is treated with 2ml of Potassium iodide solution.	Absence of white precipitate	Absent

RESULT:

The given sample Kana nei contains

ACID RADICALS:

Chlroide

BASIC RADICALS:

Iron, Calcium, Starch, Reducing sugar.

PHYTOCHEMICAL ANALYSIS

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for coumarins:

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for saponins:

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for tannins:

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for flavonoids:

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols:

Lead acetate test: To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids:

To the test sample, 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Triterpenoids

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins

A. Aanthocyanin:

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100^{o}C. Formation of bluish green colour indicates the presence of anthocyanin.

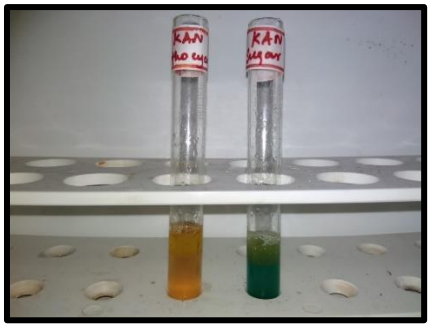
Test for Carbohydrates - Benedict's test

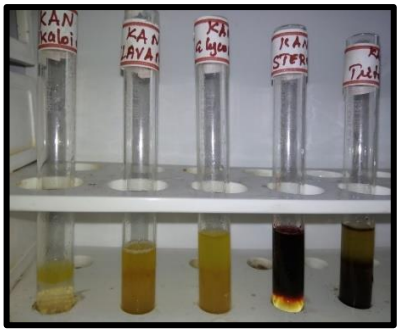
To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

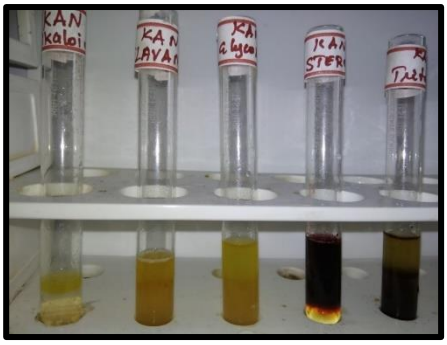
Proteins (Biuret Test)

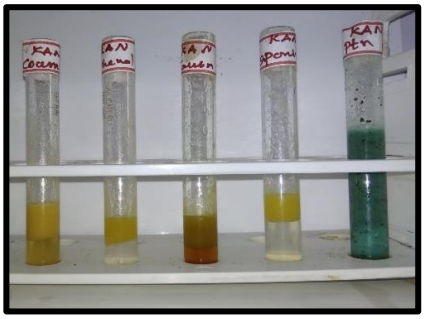
To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

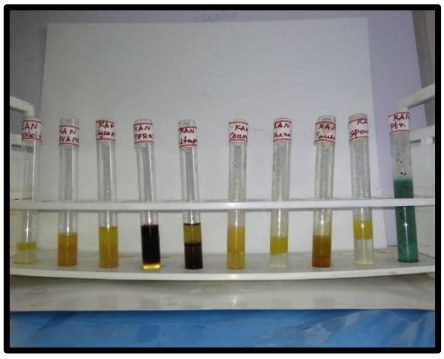
RESULTS











Test for Alkaloids, Flavonoids, Glycosides, Steroids ,Triterpenoids Coumarins, Phenol, Tanins, Saponin and Proteins, Antho Cyanin and carbohydrates.

Phytochemical Analytical Report

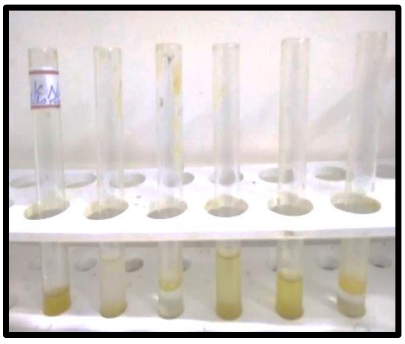
S.NO	TEST	OBSERVATION
1	ALKALOIDS	
2	FLAVANOIS	+
3	GLYCOSIDES	+
4	STEROIDS	+
5	TRITERPENOIDS	+
6	COUMARIN	+
7	PHENOL	+
8	TANIN	-
9	PROTEIN	-
10	SAPONINS	-
11	SUGAR	+
12	ANTHOCNIN	-
13	BETACYANIN	+

+ -> Indicates Positive and - -> Indicates Negative

PHYSICOCHEMICAL ANALYSIS

Sample Description

Solubility profile of KAN



State	Semi solid
Appearance	Pale Brownish
Odour	Characteristic odor
Nature	Greasy

S.No	Solvent Used	Solubility / Dispersibility
1	Chloroform	Soluble
2	Ethanol	Insoluble
3	Water	Insoluble
4	Ethyl acetate	Soluble
5	Hexane	Soluble
6	DMSO	Insoluble

Determination of Iodine value

About 20 gm of test sample was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about 25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for an hour. About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point.

Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2 gm of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeat the same procedure with out taking the sample for blank titration . Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

Determination of Viscosity value

Viscosity determination were been carried out using Ostwald viscometers. Measurement of viscosity involves the determination of the time required for a given volume of liquid to flow through a capillary. The liquid is added to the viscometer, pulled into the upper reservoir by suction, and then allowed to drain by gravity back into the lower reservoir. The time that it takes for the liquid to pass between two etched marks, one above and one bellow the upper reservoir, is measured.

Determination of Refractive Index

Determination of RL was carried out using Refractometer.

Determination of Weight per ml

Weight per ml was determined using the comparative weight calibration method, in which the weight of 1ml of the base of the formulation was calculated and then weight of 1 ml of finished formulation were been calculated. The difference between weight variations of the base with respect to finished formulation calculated as an index of weight per ml.

Acid Value

Accurately 5 g of test sample was weighed and transferred into a 250 mL conical flask. To this, a 50 mL of neutralized alcohol solution was added. This mixture was heated for 10 min by heating mantle. Afterwards, the solution was taken out after 10 min and 1 or 2 drops of phenolphthalein indicator was added. This solution was titrated against KOH solution from the burette. The appearance of pink color indicated the end point. The volume of consumed KOH solution was determined and the titration of test sample was carried out in triplicate and the mean of the successive readings was used to calculate the acid-value of the respective sample by following expression.

Acid value = Titter Value X 0.00561X 1000 / Wt of test sample (g)

Peroxide value

5 g of the substance being examined, accurately weighed, into a 250-ml glass-stoppered conical flask, add 30 ml of a mixture of 3 volumes of glacial acetic acid and 2 volumes of chloroform, swirl until dissolved and add 0.5ml volumes of saturated potassium iodide soluton. Allow to stand for exactly 1 minute, with occasional shaking, add 30 ml of water and titrate gradually, with continuous and vigorous shaking, with 0.01M sodium thiosulphate until the yellow colour almost disappears. Add 0.5 ml of starch solution and continue the titration, shaking vigorously until the blue colour just disappears (a ml). Repeat the operation omitting the substance being examined (b ml). The volume of 0.01M sodium thiosulphate in the blank determination must not exceed 0.1 ml.

$$\text{Peroxide value} = 10\ (a - b)/w$$

Analytical Report

S.No	*Parameter*	*KAN*
1	***Viscosity at 50ºC (Pa s)***	*54.62*

2	***Refractive index***	*1.44*
3	***Weight per ml (gm/ml)***	*0.073 gm/ml*
4	***Iodoine value (mg I2/g)***	*97.155*
5	***Saponification Value (mg of KOH to saponify 1gm of fat)***	*194.56*
6	***Acid Value mg KOH/g***	*0.5049*
7	***Peroxidase Value mEq/kg***	*4.063*

TLC AND HPTLC ANALYSIS OF KANA NEI

TLC Analysis

Test sample was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with the specified solvent system After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis.

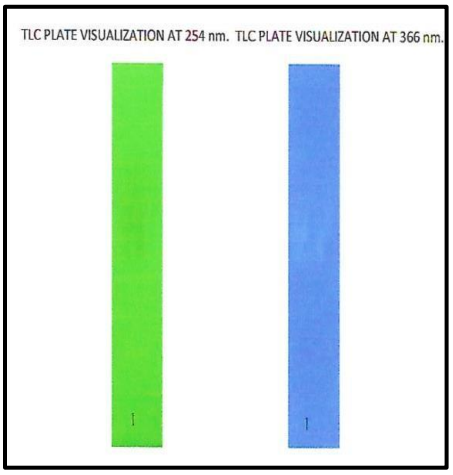
It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

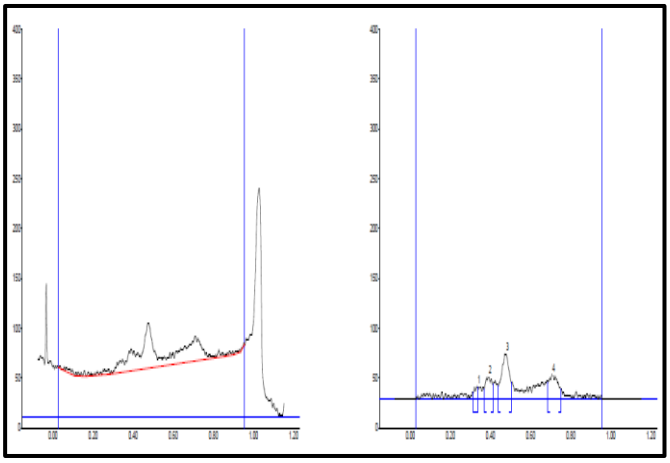
It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.



TLC ANALYSIS



HPTLC finger printing Of sample K

SPECIFIC PATHOGEN TEST FOR KANA NEI

Test for Specific Pathogen

Methodology

Test sample was directly inoculated in to the specific pathogen medium (EMB, DCC, Mannitol, Cetrimide) by pour plate method. The plates were incubated at 37ºC for 24 - 72h for observation. Presence of specific pathogen identified by their characteristic color with respect to pattern of colony formation in each differential media.

Detail of Specific Medium and their abbreviation

Organism	Abbreviation	Medium
E-coli	***EC***	***EMB Agar***
Salmonella	***SA***	***Deoxycholate agar***
Staphylococcus Aureus	***ST***	***Mannitol salt agar***
Pseudomonas Aeruginosa	***PS***	***Cetrimide Agar***

Observation

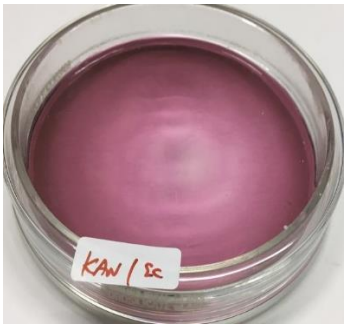
No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

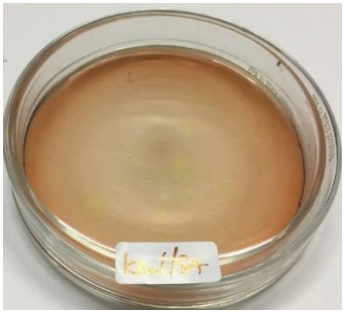
No growth / colonies were observed in any of the plates inoculated with the test sample.

Organism	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

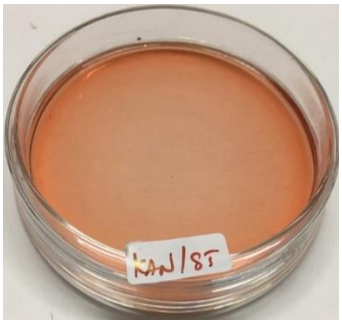
Culture plate with Pseudomonas Aeruginosa (PS) specific medium



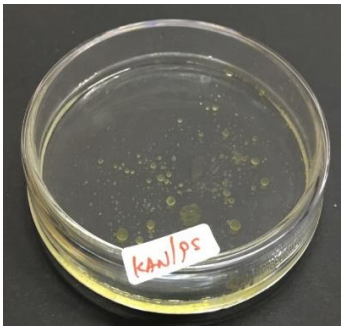
Culture plate with Salmonella (SA) specific medium

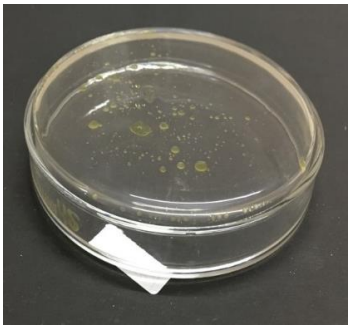


Culture plate with Staphylococcus Aureus (ST) specific medium



Culture plate with Pseudomonas Aeruginosa (PS) specific medium





STERILITY TEST FOR KANA NEI

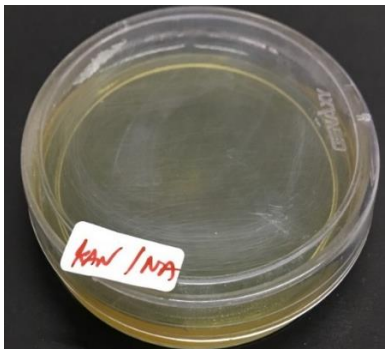
STERILITY TEST BY POUR PLATE METHOD

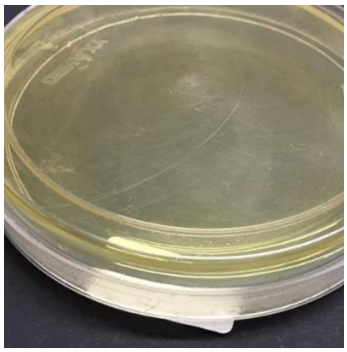
Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated / un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Methodology

Test sample was admixed with sterile distilled water and the mixture were been used for the sterility evaluation. About 1ml of the test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45ºC were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37º C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.





Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

No growth / colonies were observed in any of the plates inoculates with the test sample.

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^5CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^3CFU/g	

HEAVY METAL ANALYSIS BT AAS

Standard: Hg, As, Pb and Cd – Sigma

Methodology

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test item.

Sample Digestion

Test sample was digested with 1mol/L HCl for determination of arsenic and mercury. Similarly for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3.

Standard reparation

As & Hg- 100 ppm sample in 1mol/L HCl
Cd & pb – 100 ppm sample in mol/L HNO_3

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis	Maximum Limit
Mercury	253.7 nm	BDL	1 ppm
Lead	217.0 nm	BDL	10 ppm
Arsenic	193.7 nm	BDL	3 ppm
Cadmium	228.8 nm	BDL	0.3 ppm

BDL - Below Detection limit

Report and inference

- Results of the present investigation have clearly shows that the sample has no traces of heavy metals such as Mercury, Arsenic, Cadmium and Lead.

ANALYSIS OF PESTICIDE ORGANOCHLORINE, ORGANOPHOSPHORUS AND PYRETHROIDS

Extraction

Test sample were extracted with 100 ml of acetone and followed by homogenization for brief period. Further filtration was allowed and subsequent addition of acetone to the test mixture. Heating of test sample was performed using a rotary evaporator at a temperature not exceeding 40ºC until the solvent has almost completely evaporated. To the residue add a few milliliters of toluene R and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter.

Test Result Analysis of the Sample KAN

Pesticide Residue I .Organo Chlorine Pesticides	Sample KAN	AYUSH Limit (mg/kg)
Alpha BHC	BQL	0.1mg/kg
Beta BHC	BQL	0.1mg/kg
Gamma BHC	BQL	0.1mg/kg
Delta BHC	BQL	0.1mg/kg
DDT	BQL	1mg/kg
Endosulphan	BQL	3mg/kg
II.Organo Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
III.Pyrethroid		
Cypermethrin	BQL	1mg/kg

BQL- Below quantification Limit

Result: The results showed that there were no traces of pesticides residues such as Organo chlorine, Organo phosphorus and pyrethroids in the sample provided for analysis.

AFLATOXIN STUDY FOR KANA NEI

Standard

Aflatoxin B1

Aflatoxin B2

Aflatoxin G1

Aflatoxin G2

SOLVENT

Standard samples was dissolved in a mixture of chloroform and acetonitrile (9.8:0.2) to obtain a solution having concentration of 0.5 µg per ml each of aflatoxin B1 and aflatoxin G1 and 0.1 µg per ml each of aflatoxin B2 and aflatoxin G2

TEST SOLUTION: Concentration 1 µg per ml

PROCEDURE

Standard aflatoxins was applied on to the surface to pre coated TLC plate in the volume of 2.5 µL, 5 µL,7.5 µL and 10 µL.Similarly the test sample was placed and Allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of chloroform, acetone and isopropyl alcohol (85:10:5) until the solvent front has moved not less than 15cm from the origin. Remove the plate from the developing chamber, mark the solvent from and allow the plate tp air- dry. Locate the spots on the plate by examination under UV light at 365nm.

Aflatoxin	Sample KAN	AYUSH Specification Limit
B1	Not Detected - Absent	0.5 ppm
B2	Not Detected - Absent	0.1 ppm
G1	Not Detected - Absent	0.5 ppm
G2	Not Detected - Absent	0.1 ppm

RESULT:

The results shown that there was no spots were been identified in the test sample loaded on TLC plates when compare to the standard, which indicates that the sample were free from aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2.

ACUTE ORAL TOXICITY STUDY OF KANA NEI (OECD GUIDELINE-423)

Introduction:

- The acute toxic class method is a stepwise procedure with the use of 3 animals of a single sex per step.
- Depending on the mortality and/or the moribund status of the animals, on average 2-4 steps may be necessary to allow judgement on the acute toxicity of the test substance.
- This procedure is reproducible, uses very few animals and is able to rank substances in a similar manner to the other acute toxicity testing methods.
- The acute toxic class method is based on biometric evaluations with fixed doses, adequately separated to enable a substance to be ranked for classification purposes and hazard assessment.
- In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.
- The method allows for the determination of an LD50 value only when at least two doses result in mortality higher than 0% and lower than 100%.
- The use of a selection of pre-defined doses, regardless of test substance, with classification explicitly tied to number of animals observed in different states improves the opportunity for laboratory to laboratory reporting consistency and repeatability.

Principle of the Test:

It is the principle of the test that based on a stepwise procedure with the use of a minimum number of animals per step, sufficient information is obtained on the acute toxicity of the test substance to enable its classification. The substance is administered orally to a group of experimental animals at one of the defined doses. The substance is tested using a stepwise procedure, each step using three animals of a single sex. Absence or presence of compound-related mortality of the animals dosed at one step

will determine the next step, i.e.

− no further testing is needed

− dosing of three additional animals, with the same dose

− dosing of three additional animals at the next higher or the next lower dose level. The method will enable a judgment with respect to classifying the test substance to one of a series of toxicity classes.

Methodology:

Selection of Animal Species

The preferred rodent species is the wistar albino rat, although other rodent species may be used. Healthy young adult animals are commonly used laboratory strains should be employed. Females should be nulliparous and non-pregnant. Each animal, at the commencement of its dosing, should be between 6 to 8 weeks old and the weight (150-200gm) should fall in an interval within±20 % of the mean weight of any previously dosed animals.

Housing and Feeding Conditions

The temperature in the experimental animal room should be 22ºC ± 3ºC. Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning the aim should be 50-60%. Lighting should be artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. Animals may be group-caged by dose, but the number of animals per cage must not interfere with clear observations of each animal.

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Test Animals and Test Conditions:

Sexually mature Female Wistar albino rats (150-200gm) were obtained from TANUVAS, Madhavaram, Chennai. All the animals were kept under standard

environmental condition (22±3°C). The animals had free access to water and standard pellet diet (Sai meera foods, Bangalore).

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Preparation for Acute Toxicity Studies

Rats were deprived of food overnight (but not water 16-18 h) prior to administration of the,***KANA NEI***.

The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of the animals and the study design

IAEC Approved Number: LV/10/CLBMCP/2018

Test Substance	: **KANA NEI**
Animal Source	: TANUVAS,Madhavaram, Chennai.
Animals	: Wister Albino Rats (Female-3+3)
Age	**:** 6-8 weeks
Body Weight on Day 0	**:** 150-200gm.
Acclimatization	**:** Seven days prior to dosing.
Veterinary examination	**:** Prior and at the end of the acclimatization period.
Identification of animals	**:** By cage number, animal number and individual marking by using Picric acid.
Number of animals	: 3 Female/group,
Route of administration	: Oral
Diet	**:** Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore
Water	**:** Aqua guard portable water in polypropylene bottles.

Housing & Environment **:** The animals were housed in Polypropylene cages provided with bedding of husk.

Housing temperature **:** between 22ºC ± 3ºC.

Relative humidity **:** between 30% and 70%,

Air changes **:** 10 to 15 per hour and

Dark and light cycle **:** 12**:**12 hours.

Duration of the study **:** 14 Days

Administration of Doses:

KANA NEI was suspended in water and administered to the groups of wistar albino rats in a single oral dose by gavage using a feeding needle. The control group received an equal volume of the vehicle. Animals were fasted 12 hours prior to dosing. Following the period of fasting, the animals were weighed and then the test substance was administered. Three Female animals are used for each group. The dose level of 5, 50, 300 and 2000 mg/kg body weight was administered stepwise. After the substance has been administered, food was withheld for a further 3-4 hours. The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously as per the guideline after substance administration. The visual observations included skin changes, mobility, aggressively, sensitivity to sound and pain, as well as respiratory movements. Finally, the number of survivors was noted after 24 hrs and these animals were then monitered for a further 14 days and observations made daily. The toxicological effect was assessed on the basis of mortality.

Observations:

Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours, and daily thereafter, for a total of 14 days, except where they need to be removed from the study and humanely killed for animal welfare reasons or are found dead. It should be determined by the toxic reactions, time of onset and length of recovery period, and may thus be extended when considered necessary. The times at

which signs of toxicity appear and disappear are important, especially if there is a tendency for toxic signs to be delayed. All observations are systematically recorded with individual records being maintained for each animal.

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behavior pattern. Attention was directed to observations of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanly killed. When animals are killed for human reasons or found dead, the time of death was recorded.

Acute oral toxicity study of KANA NEI

Table 1: Dose finding experiment and its behavioral Signs of acute oral Toxicity

Observation done:

SL	Group CONTROL	Observation	SL	Group TEST GROUP	Observation
1	Body weight	Normal	1	Body weight	Normally increased
2	Assessments of posture	Normal	2	Assessments of posture	Normal
3	Signs of Convulsion Limb paralysis	Normal	3	Signs of Convulsion Limb paralysis	Absence of sign (-)
4	Body tone	Normal	4	Body tone	Normal
5	Lacrimation	Normal	5	Lacrimation	Absence

6	Salivation	Normal	6	Salivation	Absence
7	Change in skin color	No significant color change	7	Change in skin color	No significant color change
8	Piloerection	Normal	8	Piloerection	Normal
9	Defecation	Normal	9	Defecation	Normal
10	Sensitivity response	Normal	10	Sensitivity response	Normal
11	Locomotion	Normal	11	Locomotion	Normal
12	Muscle gripness	Normal	12	Muscle gripness	Normal
13	Rearing	Mild	13	Rearing	Mild
14	Urination	Normal	14	Urination	Normal

Behaviour:

The animals will be observed closely for behaviour in the first four hours which includes abnormal gait, aggressiveness, exophthalmos, ptosis, akinesia, catalepsy, convolusion, excitation, head twitches, lacrimation, loss of corneal reflex, loss of traction, piloerection reactivity of touch, salivation, scratching, sedation, chewing, head movements, sniffing, straub, tremor and writhes, diarrhea, leathery, sleep and coma.

Body Weight:

Individual weight of animals was determined before the test substance was administered and weights will be recorded at day 1, 7, and 14 of the study. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and humanly killed.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Mortality:

Animals were observed for mortality throughout the entire period.

Results:

All data were summarized in tabular form, (Table-1-4) showing for each test group the number of animals used, the number of animals displaying signs of toxicity, the number of animals found dead during the test ,description of toxic symptoms,, weight changes, food and water intake

No of animals in each group:3

Table 2 (Observational study Results)

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	**Control**	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.	**2000mg**	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

1..Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhea 18. Writhing

19. Respiration 20. Mortality.

(+ Present, - Absent)

Table 3 (Body weight Observation)

DOSE	DAYS		
	1	7	14
CONTROL	240.2±12.30	261.4 ± 14.12	276.6 ±16.18
HIGH DOSE	224.4± 14.22	228 ± 3.14	232.4 ± 2.22
P value (p)*	NS	NS	NS

Table 4 (Water intake (ml/day) of Wistar albino rats group exposed to *KANA NEI):*

DOSE	DAYS		
	1	6	14
CONTROL	81 ± 2.12	84±2.32	88.8±1.24
HIGH DOSE	72.2±1.1	74.2±1.24	78.20±33
P value (p)*	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 5: Food intake (gm/day) of Wistar albino rats group exposed to *KANA NEI*

DOSE	DAYS		
	1	7	14
CONTROL	96.24±1.32	96.2±1.46	98.4±3.26
High DOSE	78.2±1.42	74.6±2.32	72.1±2.28

REPEATED DOSE 28-DAYS ORAL TOXICITY (407)

STUDY OF KANA NEI

Test Substance : **KANA NEI**

Animal Source : TANUVAS, Madhavaram, Chennai.

Animals : Wister Albino Rats (Male -24, and Female-24)

Age **:** 6-8 weeks

Body Weight **:** 150-200gm.

Acclimatization **:** Seven days prior to dose.

Veterinary examination **:** Prior and at the end of the acclimatization period.

Identification of animals **:** By cage number, animal number and individual marking by using Picric acid

Diet **:** Pellet feed supplied by Sai Meera Foods Pvt Ltd, Bangalore

Water **:** Aqua guard portable water in polypropylene bottles.

Housing & Environment **:** The animals were housed in Polypropylene cages provided with bedding of husk.

Housing temperature **:** between 22ºC±3ºC.

Relative humidity **:** between 30% and 70%,**Air changes** **:** 10 to 15 per hour

Dark and light cycle **:** 12**:**12 hours.

Duration of the study **: 28 Days.**

Table 6

Groups	**No of Rats**
Group I Vehicle control (Water)	12(6male,6 female)
Group II KN - low dose X (30mg)	12 (6male,6 female)
Group III KN - Mid dose 5X (150mg)	12 (6male,6female)
Group IV KN - High dose 10X(300mg)	12(6male,6female)

KN - KANA NEI

Methodology

Randomization, Numbering and Grouping of Animals:

48 Wistar Albino Rats (24M + 24F) were selected and divided into 4 groups. Each group consist of 12 animals (Male -6, and Female-6). First group treated as a control and other three group were treated with test drug (low, mid, high) for 28 days. Animals were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal was marked with picric acid. The females were nulliparous and non-pregnant.

Justification for Dose Selection:

As per OECD guideline three dose levels were selected for the study. They are low dose (X), mid dose (5X), high dose (10X). X is calculated by multiplying the acute toxicity dose 2000mg) and the body surface area of the rat (0.018). i.e X dose is (30mg/kg), 5X dose is (150mg/kg), 10X dose is (300mg/kg).

Preparation and Administration of Dose:

KANA NEI suspended in with water, It was administered to animals at the dose levels of X, 5X, 10X. The test substance suspensions were freshly prepared every two days once for 28 days. The control animals were administered vehicle only. The drug was administered orally by using oral gavage once daily for 28 consecutive days.

Observations:

Experimental animals were kept under observation throughout the course of study for the following:

Body Weight:

Weight of each rat was recorded on day 0, at weekly intervals throughout the course of study.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Clinical signs:

All animals were observed daily for clinical signs. The time of onset, intensity and duration of these symptoms, if any, were recorded.

Mortality:

All animals were observed twice daily for mortality during entire course of study.

Necropsy:

All the animals were sacrificed by excessive anesthesia on day 29. Necropsy of all animals was carried out.

Laboratory Investigations:

Following laboratory investigations were carried out on day 29 in animals fasted over-night. Blood samples were collected from orbital sinus using sodium heparin (200IU/ml) for Bio chemistry and potassium EDTA (1.5 mg/ml) for Hematology as anticoagulant. Blood samples were centrifuged at 3000 r.p.m. for 10 minutes.

Haematological Investigations:

Haematological parameters were determined using Haematology analyzer.

Biochemical Investigations:

Biochemical parameters were determined using auto-analyzer.

Histopathology:

Control and highest dose group animals will be initially subjected to histopathological investigations. If any abnormality found in the highest dose group than the low, then the mid dose group will also be examined. Organs will be collected from all animals and preserved in 10% buffered neutral formalin for 24 h and washed in running water for 24 h. The organ sliced 5 or 6µm sections and were dehydrated in an auto technicon and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" moulds. It was followed by microtome and the slides were stained with Haematoxylin-eosin red.

Statistical analysis:

Findings such as body weight changes, water and food consumption, hematology and blood chemistry were subjected to One-way ANOVA followed by dunnet t test using a computer software programme – Graph pad version 7. All data were summarized in tabular form, (Table-6 to 12)

RESULTS:

Repeated Dose 28- day oral toxic study of KANA NEI

Table 7: Body weight of wistar albino rats group exposed to *KANA NEI*

DOSE	DAYS				
	1	7	14	21	28
CONTROL	282.2±05.64	282.2 ± 10.04	282.4 ± 12.40	282.4± 14.40	282.2 ± 12.10
LOW DOSE	280.7 ± 57.75	280.4 ± 4.19	281.3± 5.21	282 ±1.40	282.6± 6.16
MID DOSE	281.1± 1.22	281.2 ± 2.21	281.2 ± 1.42	282.2 ± 5.08	282.4 ± 13.12
HIGH DOSE	275.2± 2.41	275.4±3.17	275.8 ± 2.64	276.2 ± 4.18	277 ± 3.30
P value (p)*	NS	NS	NS	NS	NS

NS- Not Significant, **(p > 0.01),*(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 8: Water intake (ml/day) of Wistar albino rats group exposed to *KANA NEI*

DOSE	DAYS				
	1	6	14	21	28
CONTROL	56.4 ± 2.34	56.2±1.07	56.7±1.30	56.8±1.10	56.4±1.70
LOW DOSE	63.6±1.81	63.6±2.43	63.6±1.72	63.7±2.36	63.7±1.30
MID DOSE	64.2±2.21	64.2±1.21	64.1±2.52	64.4±1.42	64.4±1.74
HIGH DOSE	58.2±3.40	58.2±1.42	58.4±1.44	58.6±1.78	58.8±2.62
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 9: Food intake (gm/day) of Wistar albino rats group exposed to *KANA NEI*

DOSE	DAYS				
	2	7	23	22	28
CONTROL	61±3.01	61.2±2.11	61.4±3.11	61.4.2±3.42	61±3.40
LOW DOSE	59.5±7.12	59.5±1.44	59.6±1.50	59.4±1.20	59.8±1.92
MID DOSE	60.2±6.70	60.2±2.20	60.6±2.24	60.6±1.46	60.7±1.74
HIGH DOSE	64.3±1.55	64.6±1.54	64.8±2.16	65.1±1.50	65.1±1.72
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

Table 10: Haematological parameters of Wistar albino rats group exposed to *KANA NEI*

Category	Control	Low dose	Mid dose	High dose	P value (p)*
Haemoglobin(g/dl)	34.6±0.43	34.6±0.30	34.6±0.13	34.6±0.23	N.S
Total WBC ($\times 10^3$ l)	9.1±0.40	9.12±0.01	9.1±0.08	9.13±1.30	N.S
Neutrophils (%)	15.1±0.20	15.12±0.23	15.13±1.06	15.14±1.07	N.S
lymphocyte (%)	80.10±1.36	80.10±1.20	80.12±1.24	81.20±1.34	N.S
Monocyte (%)	0.01±0.02	0.01±0.01	0.01±0.04	0.01±0.03	N.S
Eosinophil (%)	0.04±0.06	0.04±0.03	0.04±0.05	0.04±0.07	N.S

Platelets cells10^3/µl	1400.1±1.08	1400.3±4.84	1400.2±4.60	1400.4±6.32	N.S
Total RBC 10^6/ µl	9.32±0.64	9.32±0.652	9.65±0.08	9.66±0.05	N.S
PCV%	34.60±0.8	34.63±6.23	34.6±1.31	34.8±8.22	N.S
MCHC g/dL	35.2±1.42	35.4±1.22	35.6±1.52	35.8±1.23	N.S
MCV fL(µm^3)	54.8±1.21	54.8±1.20	54.6±1.11	54.7±1.10	N.S

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 11: Biochemical Parameters of of Wistar albino rats group exposed to *KANA NEI*

BIOCHEMICAL PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
GLUCOSE (R) (mg/dl)	85.10±1.22	85.13±1.31	85.6±.04	85.7±6.20	N.S
T.CHOLESTEROL(mg/dl)	105.10±3.10	105.15±2.20	105.10±1.17	105.11±13	N.S
TRIGLY(mg/dl)	76.03±1.04	76.04±1.32	76.05±1.32	76.06±1.04	N.S
LDL	69.2±4.13	69.4±1.45	69.3±1.23	69.4±2.22	NS
VLDL	14.6±1.30	14.6±1.42	14.6±1.22	14.4±1.24	NS
HDL	24.12±2.30	24.12±2.30	24.16±1.42	24.65±1.34	NS
Ratio 1(T.CHO/HDL)	5.1±1.10	5.1±1.20	5.1±1.30	5.1±1.60	NS
Ratio 2(LDL/HDL)	2.85±2.13	2.85±1.20	2.85±2.20	2.85±04.02	NS
Albumin (g/dL)	3.2±0.10	3.2±0.64	3.2±4.80	3.3±3.24	NS

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 12: Renal function test of of Wistar albino rats group exposed to *KANA NEI*

PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
UREA (mg/dl)	22.11±0.10	22.10±0.15	22.16±1.22	22.12±1.63	N.S
CREATININE(mg/dl)	0.6±0.02	0.6±0.03	0.6±0.05	0.6±0.09	N.S
BUN(mg/dL)	27.5±0.03	27.5±0.14	27.8±0.30	27.8±1.40	NS
URIC ACID(mg/dl)	6.04±0.02	6.1±0.20	6.1±0.30	6.2±0.60	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05) , n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 13: Liver Function Test of of Wistar albino rats group exposed to *KANA NEI*

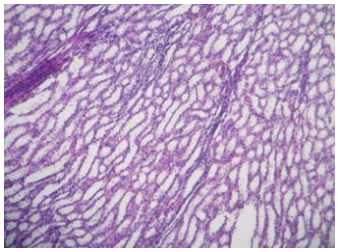
PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
T BILIRUBIN(mg/dl).	0.07±0.07	0.07±0.02	0.07±0.04	0.07±0.01	N.S
SGOT/AST(U/L)	132.1±1.33	132.2±0.32	132.4±1.33	132.6±1.43	N.S
SGPT/ALT(U/L)	99.10±1.44	99.14±1.10	99.24±1.64	99.23±0.20	N.S
ALP(U/L)	182.40±1.12	182.2±1.14	183±1.24	184.3±2.51	N.S
T.PROTEIN(g/dL)	6.5±0.13	6.5±0.21	6.7±0.32	6.7±0.34	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

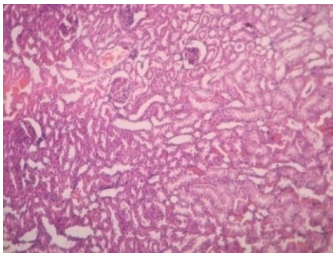
HISTO PATHOLOGY

CONTROL GROUP

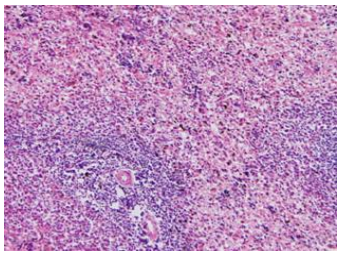
Kidney



Liver

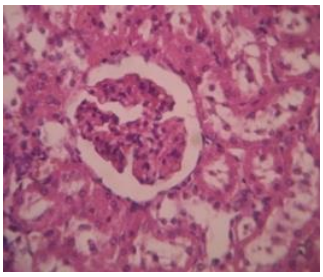


Spleen

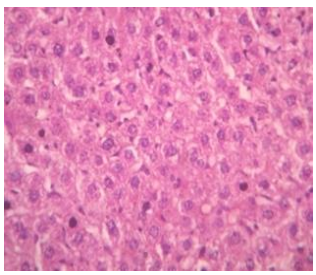


HIGH DOSE

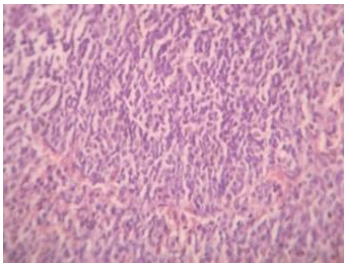
Kidney



Liver



Spleen



KANA NEI BRONCHODILATOR ACTIVITY

Bronchodilator Activity of Kana nei on Milk induced Leucocytosis and Eosinophilia method in mice model.

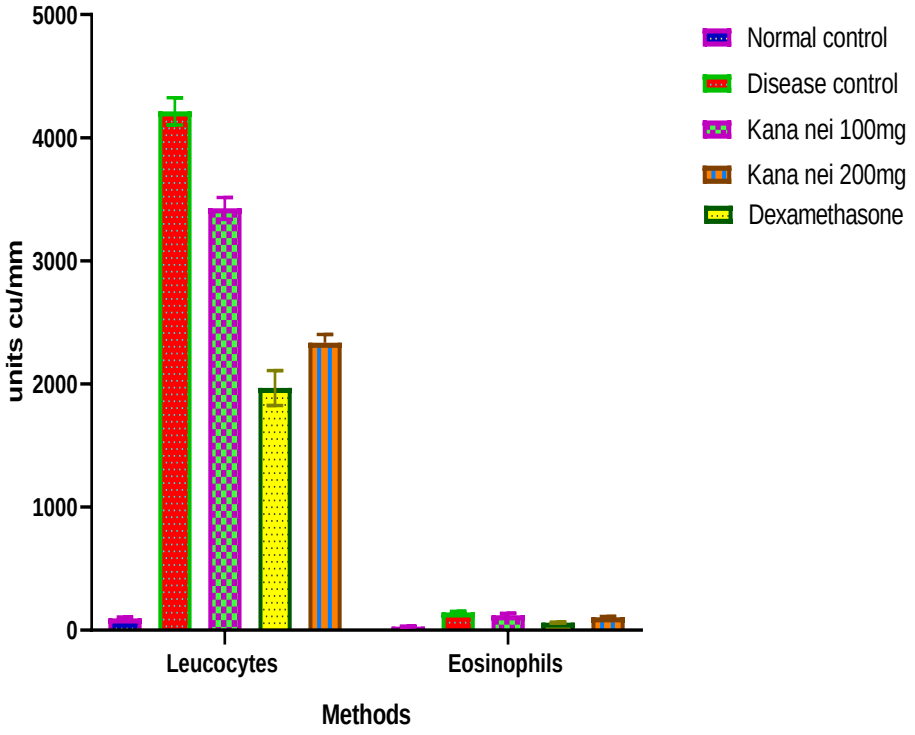
After injected of milk (4 ml/kg) to mice significant increases (P value less than 0.001) in leucocytes and eosinophils count in milk intoxicated disease control group. After the treatment *Kana nei* 100 and 200mg/kg exhibited significant reduction (P value less than 0.05) of leucocytes and eosinophils counts in mice.

Table.1: Effect of *Kana nei* on milk-induced Leukocytosis and Eosinophilia in mice

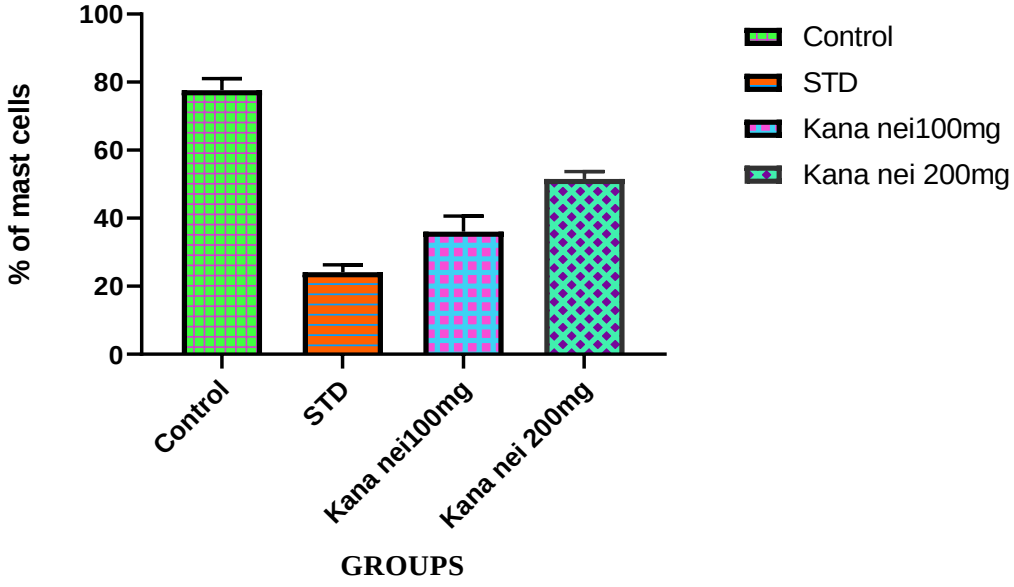
Group	Dose	Difference in no. of leucocytes (cu/mm)	Difference in no. of eosinophils (cu/mm)
1.Normal control	Distilled water, 1 ml	95±13.26	29.12±3.34
2. Disease control	Milk, 4 ml/kg	4214±111.13	145.31±9.33
3. Kana nei	100mg/kg	3426±88.75	120.56±16.34
3. *Kana nei*	200 mg/kg	2334±67.45	105.42±5.6
4. Dexamethasone	50 mg/kg	1967±142.45	60.24±4.62

Note: Values are expressed in mean ± SEM. N = 6. Comparison was done by one way ANOVA followed by Tukey – Kramer Multiple comparisons test where q value is greater than 3.958 then the P value is less than 0.05.

Effect of Kana nei on milk-induced Leukocytosis and Eosinophilia in mice



Effect of Kana nei on mast cell degranulation in mice



Mast cell stabilizing effects of Kana nei on ova albumin- induced mast cell degranulation in mice model:

Table No.2: Effect of Kana nei on mast cell degranulation in mice

Group	Dose	% Degranulation of mast cell
1. Control – Distilled water	1 ml	77.62 ±3.46
2. Standard- sodium chromoglycate	50 mg/kg	24.16±2.12
3. Kana nei	100mg/kg	36±4.65
4. *Kana nei*	200mg/kg	51.52 ± 2.21

Note: Values are expressed in mean ± SEM. N = 6.

Discussion:

Increased level of Leucocytes and eosinophils counts in our respiratory system play a vital role to induce bronchial hypersensitivity and produces airway inflammation in allergic and non-allergic asthma.

MATERIALS AND METHODS

Approval of the Screening committee and Institutional ethical committee (IEC) were obtained for undertaking the present study. **Institutional Ethical Committee (IEC) approval number is: GSMC-CH-ME-2/017/2017**

SELECTION OF PATIENTS:

The present study covers both male and female children of pediatric age groups. All cases were Carefully and thoroughly examined. Those who fulfilled the criteria of Sooli kanam according to the Clinical features in Siddha and modern reviews were selected with the aid of questionnaire. The opinion of Faculties of department was obtained and detailed history was recorded in the proforma of case sheet.

The study design and the underlying hypothesis and the rights to withdraw from the study at any time were informed orally and in writing to all the participants. A Single arm open clinical trial was undertaken in OPD of PG department of Kuzhanthai maruthuvam, Government Siddha medical college attached with Arignar Anna Hospital of Indian Medicine and Homoeopathy, Arumbakkam, chennai-106 for a period of one year. 40 patients who fulfilled the inclusion criteria were included for the study.

CLINICAL STUDIES:

After finishing the toxicity studies 40 cases were selected from the OPD of Kuzhanthai maruthuvam Department, Arignar Anna Hospital of Indian Medicine and Homoeopathy, Arumbakkam, chennai-106. They were treated with the trail drug Kana Nei and observed for prognosis clinically.

STUDY DESIGN & CONDUCT OF THE STUDY:

Study Type: An Open Clinical Trail

StudyPlace: Arignar Anna Hospital of Indian Medicine and Homoeopathy, Arumbakkam, Chennai – 600 106.

Study Period: 12 months after completion of preclinical studies.

Sample size: 40 patients.

Treatment period: 21 days

POPULATION AND SAMPLE:

1. Population consist of paediatric patients attending the OPD of Arignar Anna Hospital, GSMC, Chennai-106

2. The sample consist of patients 3 – 12 years age group fulfilling all the inclusion criteria and exclusion criteria.

STUDY PARTICIPANTS:

INCLUSION CRITERIA:

1. Age 3 to 12 years
2. Cough without expectoration
3. Dyspnea
4. Chest tightness
5. Wheezing
6. Decreased physical activity
7. Poor diet intake

EXCLUSION CRITERIA:

1.Childhood TB

2. Hypersensitivity Pneumonitis

3. Lung abscess

4. Cystic fibrosis

5. Bronchiolitis

WITHDRAWAL CRITERIA:

1.If any adverse reactions & altered symptoms occurred during the drug

trial.

2.Intolerance to the drug.

3.Patient turned unwilling to continue in the course of clinical trial.

4.Occurrence of any serious illness.

ASSESMENT AND INVESTIGATION:

CLINICAL ASSESMENT:

- Cough without expectoration
- Dyspnoea
- Running nose
- Chest tightness
- Wheezing
- Decreased physical activity
- Poor diet intake

SIDDHA DIAGNOSIS WAS MADE WITH THE HELP OF FOLLOWING METHODS:

- ❖ Poriyalarithal
- ❖ Pulanalarithal
- ❖ Vinathal
- ❖ Ennavagaithervugal (Including neerkuri, neikuri)
- ❖ Udalthathukkal
- ❖ Paruvakaalam (Season)
- ❖ Thinaigal
- ❖ Mukkutram

LAB INVETIGATION:

1,Blood:

TC

Differential WBC count

Neutrophils

Lymphocytes

Eosinophils

Monocytes

Basophils

2.ESR

½ hr& 1 hr

3.Hb

4. Urine analysis :

Albumin

Sugar

Deposits

SPECIFIC INVESTIGATION:

1.Absolute Eosinophil count.

METHODOLOGY OF TREATMENT

STUDY ENROLMENT:

Patients reporting at the OPD associated with clinical features of cough with expectoration, dyspnea, wheezing, chest tightness, running nose, decreased physical activity, poor diet intake are chosen for enrollment based on the inclusion criteria. The patient who are enrolled are informed about the study trail drug, possible outcomes of the study in the language and terms understandable to them and the informed consent/Assent would be obtained from the patient/patient's parent using consent/assent form.

CONDUCT OF THE STUDY:

The trail drug will be given in the OPD department of kuzhanthai maruthuvam, GSMC, Chennai. The patients will be asked to have a regular follow up in the OPD once in a 5days. In each and every visit the clinical assessment will be recorded in the prescribed proforma. The laboratory investigation will be done before and after treatment and recorded in the prescribed format.

DATA COLLECTION FORMS:

Required information will be collected from each patient by using following forms.

Form I: Screening and selection proforma

Form II: History taking proforma

Form III: Clinical assessment proforma

Form IV: Clinical assessment during and after trial

Form V: Laboratory Investigation proforma

Form VI: Informed consent/Assent form

Form VII: Withdrawal form

Form VIII: Patient information sheet

DATA ANALYSIS:

After enrolling the patients in the study a separate file for each patient will be maintained and all forms will be kept in the file. Whenever the patient visits OPD during the study period necessary entries will be made in the assessment forms. The data entries and adverse events if any will be monitored by the Head of the Department.

OUTCOME OF TREATMENT

Primary Outcome:

Primary outcome is mainly assessed by comparing the reduction of symptoms by scoring before and after treatment.

Secondary Outcome:

Secondary outcome is assessed by comparing the safety parameters before and after treatment.

ADVERSE EFFECT AND SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reactions the patient will be referred to the Pharmacovigilance department of SCRI, CHENNAI and documented. For any adverse effect the investigator will give the proper management in the OPD.

ETHICAL ISSUES

1. Informed consent/Assent will be obtained from the patient/patient's parent or guardian after explaining about the clinical trial in an understandable language.

2. After the consent/Assent of the patient or patients parent (through consent/Assent form) if they fit in the criteria they will be enrolled in the study.

3. Treatment will be provided free of cost.

4. The patients who are excluded (as per the exclusion criteria) will be referring to OPD.

ANALYSIS OF TRIAL MEDICINE:

1. The acute and subacute toxicity study was carried out in **C.L.Baid Metha College of Pharmacy, Thoraipakkam, Chennai-97**

2. The pharmacological analysis of trial drug for Bronchodilator activity was carried out in **C.L.Baid Metha College of Pharmacy, Thorraipakkam, Chennai-97**

3. The physiochemical and Phytochemical analysis of trialdrug was performed in **Nobel research solution, kolathur, Chennai - 99**

4. Biochemical analysis of the trial drug was performed in **GSMC, Chennai-106**

RESULTS AND OBSERVATIONS:

40 patients with confirmed diagnosis of soolikanam with satisfying the inclusion criteria wear enrolled after obtaining written informed consent and were to receive “KANA NEI” with dosage of 3 - 5 years 1gm & 6- 12 years- 2 gms twice daily for 21 days.

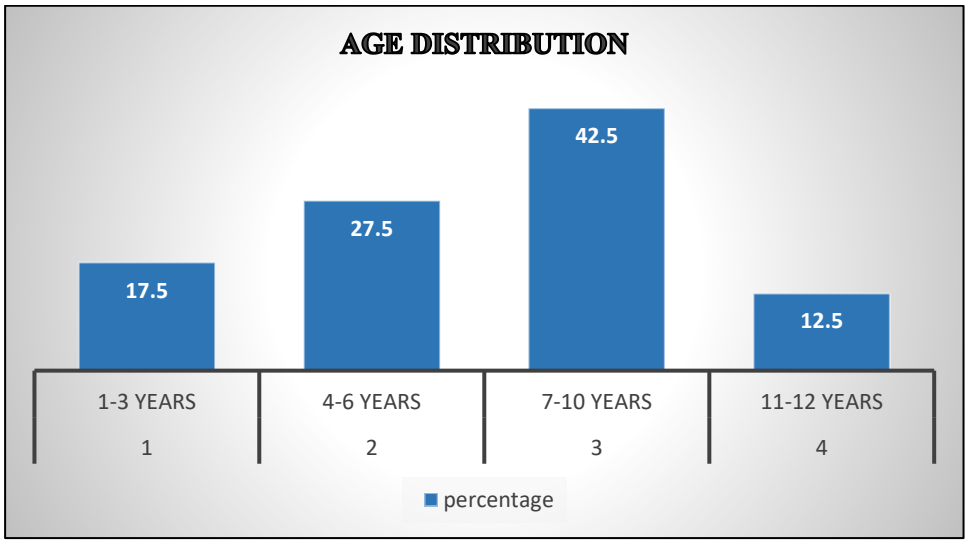
Results were observed with respect to the following criteria:

1. Age
2. Sex
3. Religion distribution
4. Family history
5. Diet history
6. Parents socio economic status
7. Paruva kaalangal
8. Mukkutram
9. 7 Udal kattugal
10. Envagai thervugal
11. Neikuri
12. Aetiological factors
13. Clinical features
14. Results
15. Investigation profile

OBSERVATIONS:

1.AGE DISTRIBUTION:

S.NO	AGE	NO. OF CASES (OUT OF 40)	PERCENTAGE
1	1 to 3 Years	7	17.5 %
2	4 to 6 Years	11	27.5 %
3	7 to 10 Years	17	42.5 %
4	11 to 12 Years	5	12.5 %

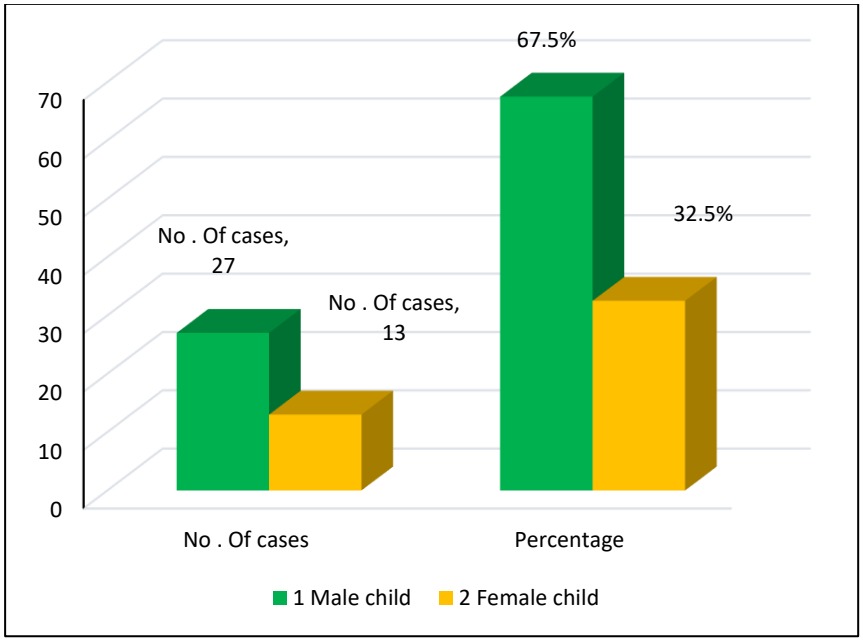


INFERENCE:

Out of 40 cases 17.5% of cases belong to age group 1-3 years, 27.5 % of cases belong to age group of 4-6 years, 42.5 % of cases belong to age group of 7-10 years and 12.5% of cases belong to age group 11-12 years.

2.SEX DISTRIBUTION:

S.NO	SEX	NO. OF CASES	PERCENTAGE
1	MALE CHILD	27	67.5%
2	FEMALE CHILD	13	32.5%

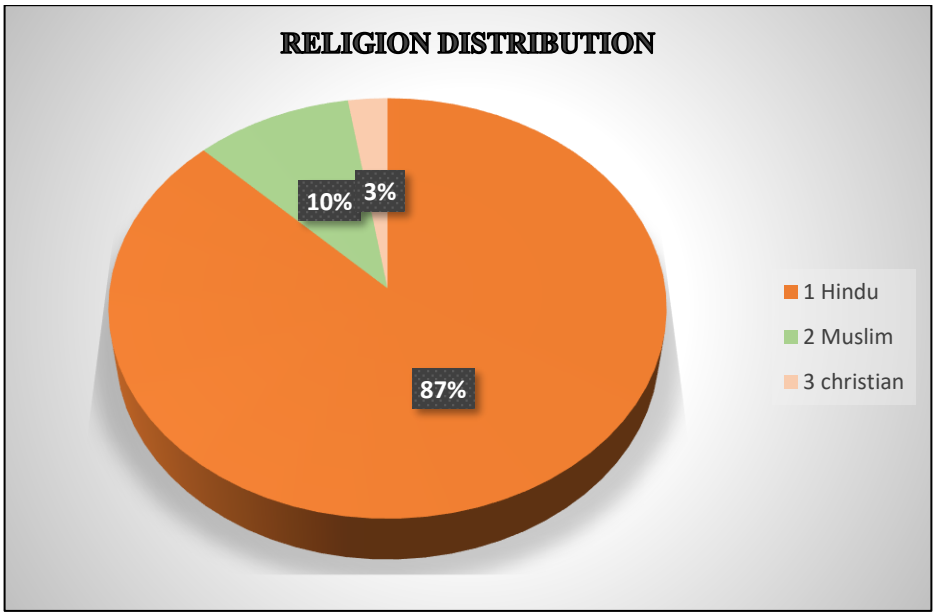


INFERENCE:

Among 40 cases of study 27 were male (67.5%) and 13 were female (32.5%)

3.RELIGION DISTRIBUTION:

S.NO	RELIGION	NO OF CASES	PERCENTAGE
1	HINDU	35	87.5%
2	MUSLIM	4	10%
3	CHRISTIAN	1	2.5%

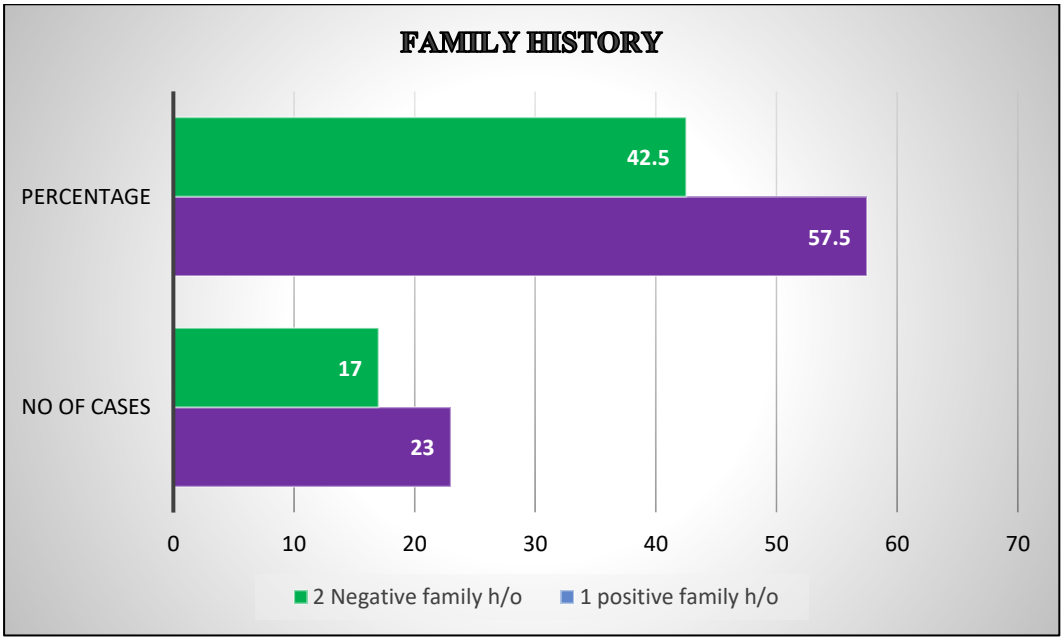


INFERENCE:

Out 40 cases 87 % were Hindu, 10 % were Muslim and 3 % were Christian

4.FAMILY HISTORY:

S.NO	FAMILY HISTORY	NO OF CASES	PERCENTAGE
1	POSITIVE	23	57.5%
2	NEGATIVE	17	42.5%

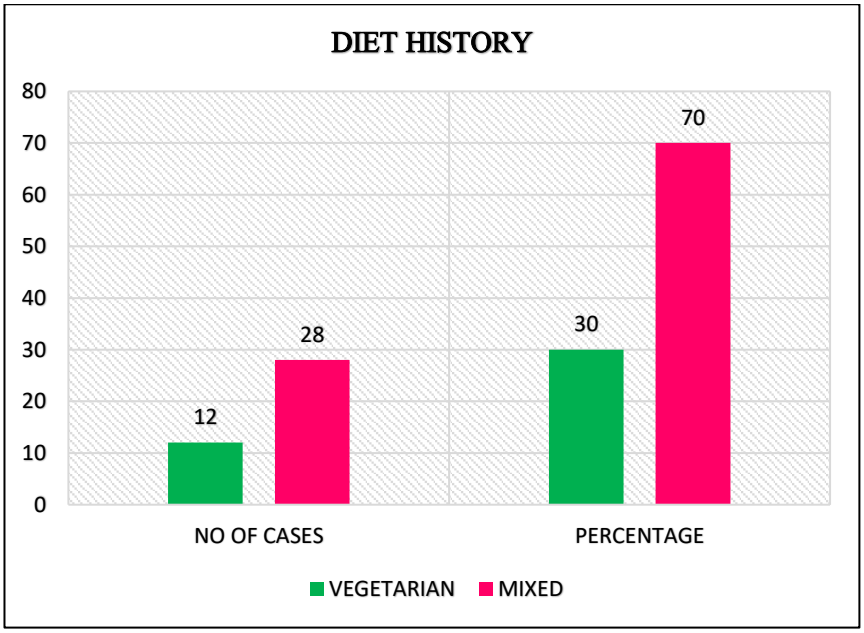


INFERENCE:

Among 40 cases (57.5%) were positive family history, (42.5%) were negative family history.

5.DIET HISTORY:

S.NO	DIET HISTORY	NO OF CASES	PERCENTAGE
1	VEGETARIAN	12	30%
2	MIXED	28	70%

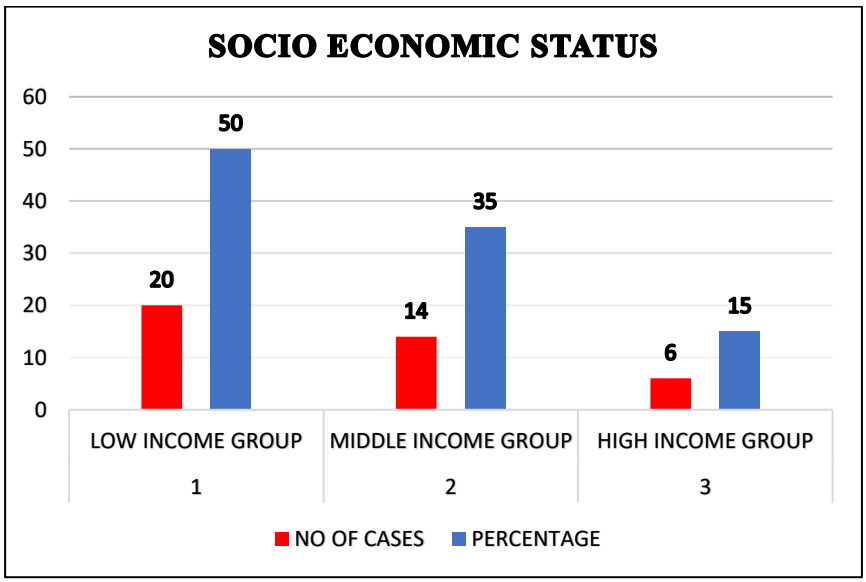


INFERENCE:

Out of 40 cases 30% were Vegetarian and remaining 70% mixed diet.

6.PARENT'S SOCIO-ECONOMIC STATUS:

S.NO	SOCIO-ECONOMIC STATUS	NO OF CASES	PERCENTAGE1
1	LOW INCOME GROUP	20	50%
2	MIDDLE INCOME GROUP	14	35%
	HIGH INCOME GROUP	6	15%

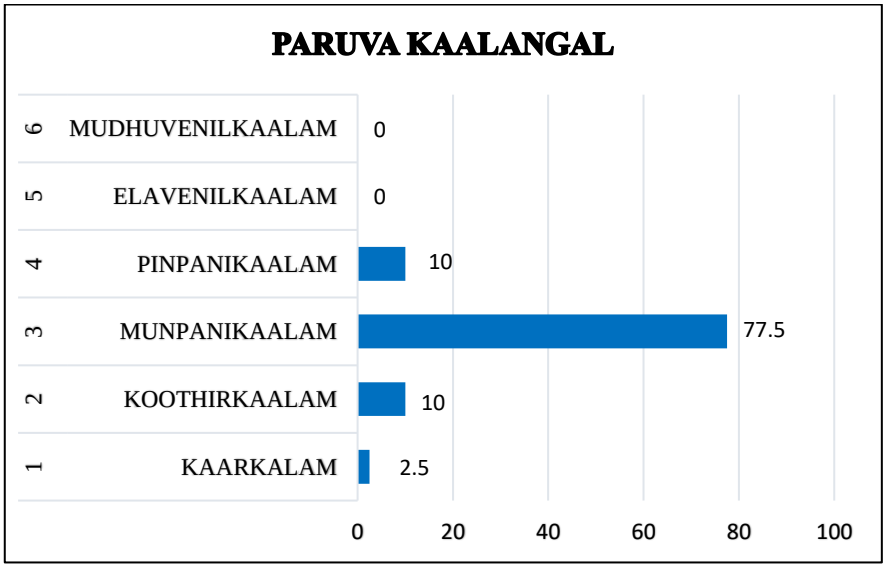


INFERENCE:

According to this study 20 cases (50%) belongs to the low income group, 14 cases (35%) belongs to the middle income group and 6 cases (15%) belongs to high income group. The highest incidence occurred in low income group.

7.DISTRIBUTION OF PARUVA KAALANGAL:

S.NO	PARUVA KAALANGAL	NO OF CASES	PERCENTAGE
1	KAAR KAALAM (Mid AUG – Mid OCT)	1	2.5%
2	KOOTHIR KAALAM (Mid OCT- Mid DEC)	4	10%
3	MUNPANI KAALAM (Mid DEC- Mid FEB)	31	77.5%
4	PINPANI KAALAM (Mid FEB- Mid APR)	4	10%
5	ELAVENIL KAALAM (Mid APR- Mid JUN)	-	-
6	MUDHUVENIL KAALAM (Mid JUN- Mid AUG)	-	-



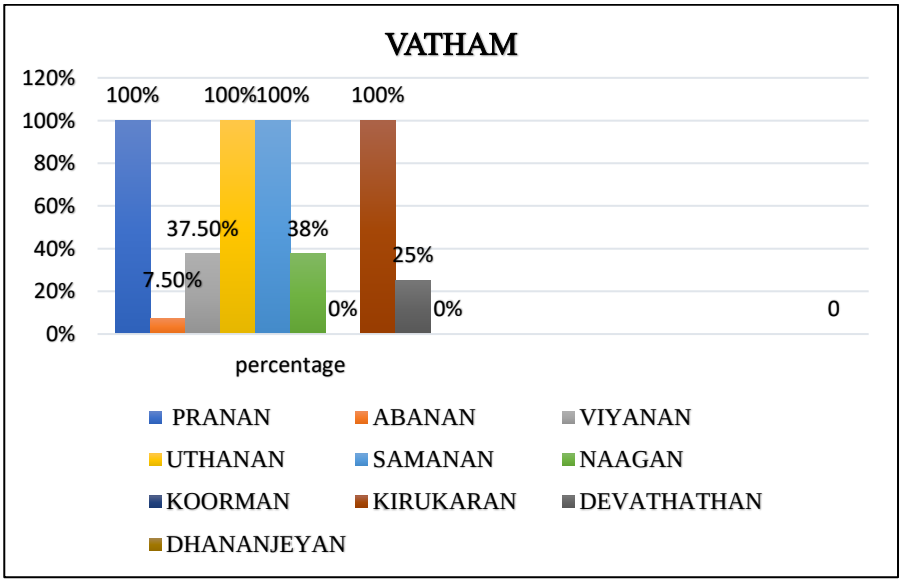
INFERENCE:

Out of 40 cases 77.5 % of cases came during Munpanikaalam, 10% of cases of the incidence come under the Koothirkaalam &Pinpanikaalam and 2.5% cases of the incidence come under Kaarkalam. The Table showed more prevalence of the disease under Munpanikaalam.

8.MUKKUTRA THEORY:

DERANGEMENT OF VATHAM:

S.NO	TYPES OF VATHAM	NO OF CASES	PERCENTAGE
1	PRANAN	40	100%
2	ABANAN	3	7.5%
3	VIYANAN	15	37.5%
4	UTHANAN	40	100%
5	SAMANAN	40	100%
6	NAAGAN	15	37.5%
7	KOORMAN	0	0
8	KIRUKARAN	40	100%
9	DEVATHATHAN	10	25%
10	DHANANJEYAN	0	0

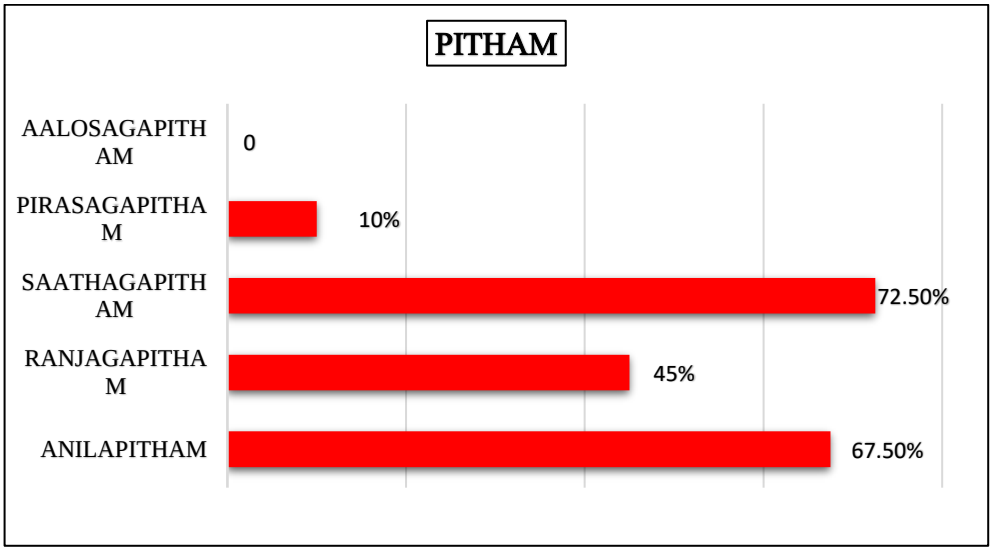


INFERENCE:

According to this Pranan, Uthanan, Samanan and kirukaran has 100 %, viyanan & Naagan has 37.5% and Devathathan have percentage of 25%. Abanan have lowest percentage of 7.5%

DERANGEMENT OF PITHAM:

S.NO	TYPES OF PITHAM	NO OF CASES	PERCENTAGE
1	ANILA PITHAM	27	67.5%
2	RANJAGA PITHAM	18	45%
3	SAATHAGA PITHAM	29	72.5%
4	PIRASAGA PITHAM	4	10%
5	AALOSAGA PITHAM	0	0

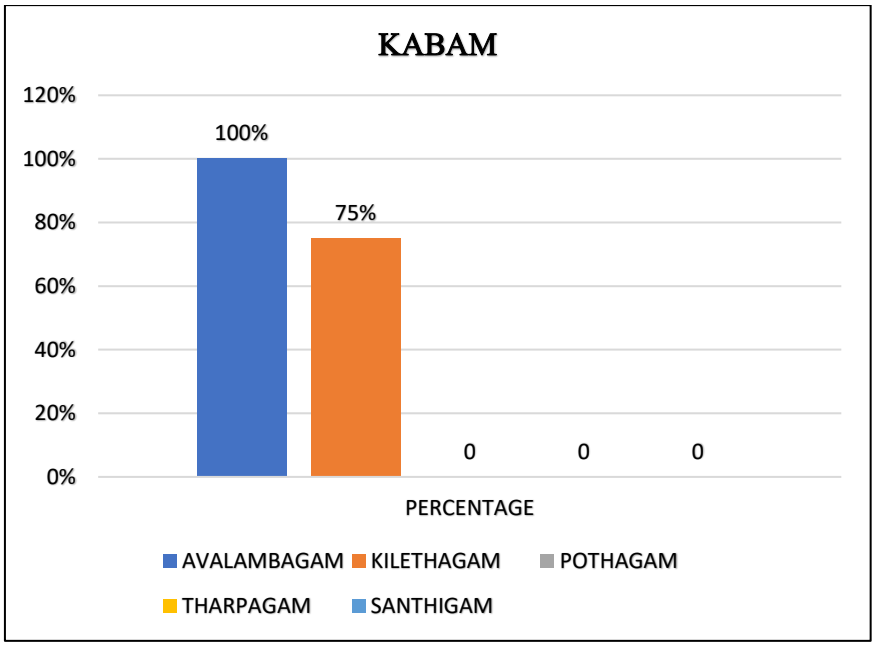


INFERENCE:

According to this, Saathagam has 72.5%, Analagam has 67.5 %, Ranjagam has 45 % and Pirasagam has 10%.

DERANGEMENT OF KABAM:

S.NO	TYPES OF KABAM	NO OF CASES	PERCENTAGE
1	AVALAMBAGAM	40	100
2	KI LETHAGAM	30	75
3	POTHIGAM	0	0
4	THARPAGAM	0	0
5	SANTHIGAM	0	0

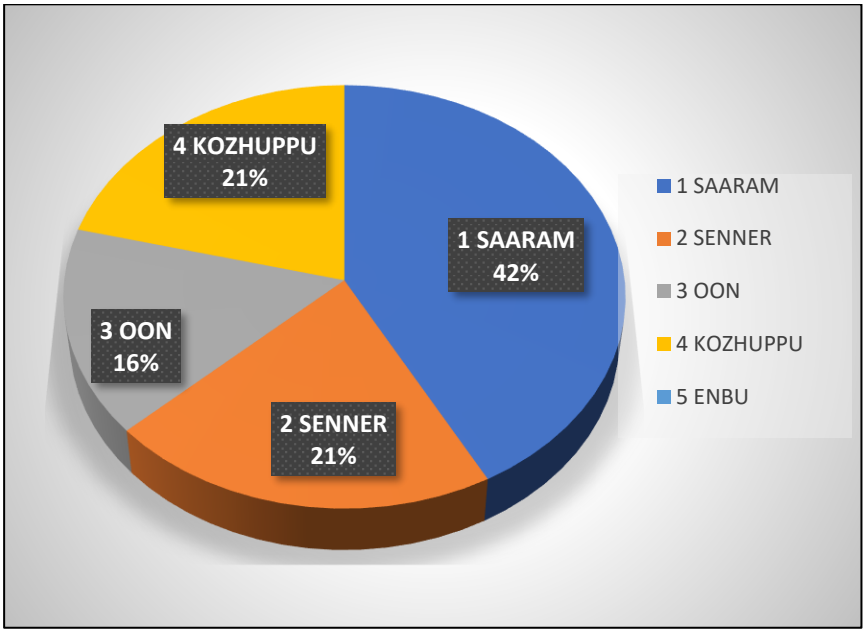


INFERENCE:

According to this,Avalambagam has 100% and Kilethakam has 75%.

9. 7 UDAL KATTUKAL:

S.NO	7UDAL KATTUKAL	NO OF CASES	PERCENTAGE
1	SAARAM	40	100%
2	SENNEER	20	50%
3	OON	15	37.5%
4	KOZHUPU	20	50%
5	ENBU	0	0
6	MOOLAI	0	0
7	SUKILAM/ SURONITHAM	0	0

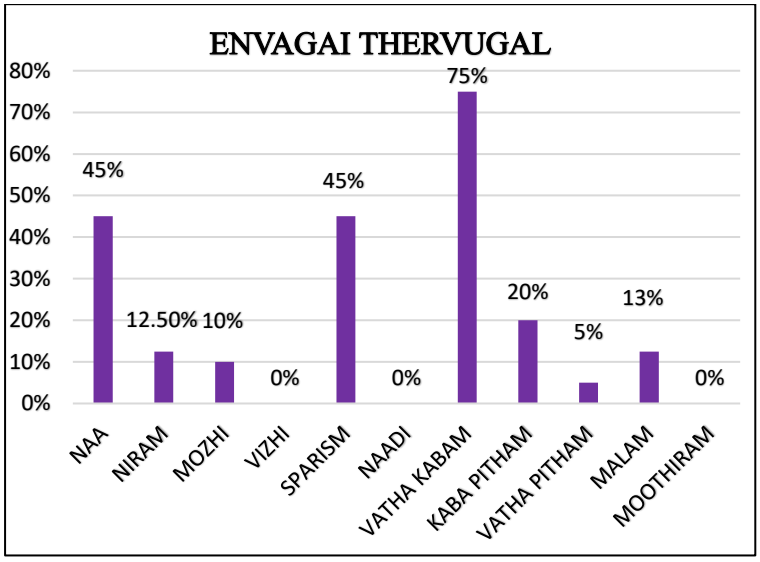


INFERENCE:

In 7 Udalkattugal 42% of the cases had derangement in Saaram, 21% of cases had derangement in Senneer & kozhuppu, 16% of cases had derangement in Oon.

10.ENVAGAI THERVUGAL:

S.NO	ENVAGAI THERVUGAL	NO OF CASES	PERCENTAGE
1	NAA	18	45%
2	NIRAM	5	12.5%
3	MOZHI	4	10%
4	VIZHI	0	0
5	SPARISAM	18	45%
6	NAADI		
A	KABA PITHAM	8	20%
B	VATHA KABAM	30	75%
C	PITHA KABAM	2	5%
7	MALAM	5	12.5%
8	MOOTHIRAM	0	0

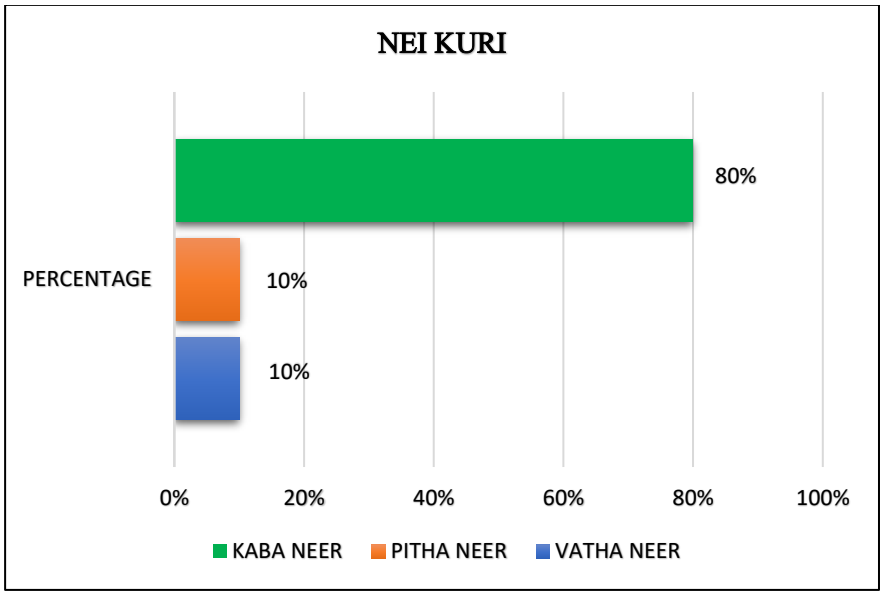


INFERENCE:

In Envagaithervugal, Naa and Sparisam were affected in 45% of cases, Niram affected in 12.5% of cases, Mozhi affected in 10% of cases, Vathakabam affected in 75% of cases, Kabapitham affected in 20% of cases and Vathapitham affected in 5% of cases. Malam affected in 13% of cases.

11.NEIKURI:

S.NO	TYPE OF URINE	CHARACTER OF URINE	NO.OF.CASES	PERCENTAGE
1	VATHANEER	SPREAD LIKE SNAKE	4	10%
2	PITHANEER	SPREAD LIKE RING	4	10%
3	KABANEER	SPREAD LIKE PEARL	32	10%

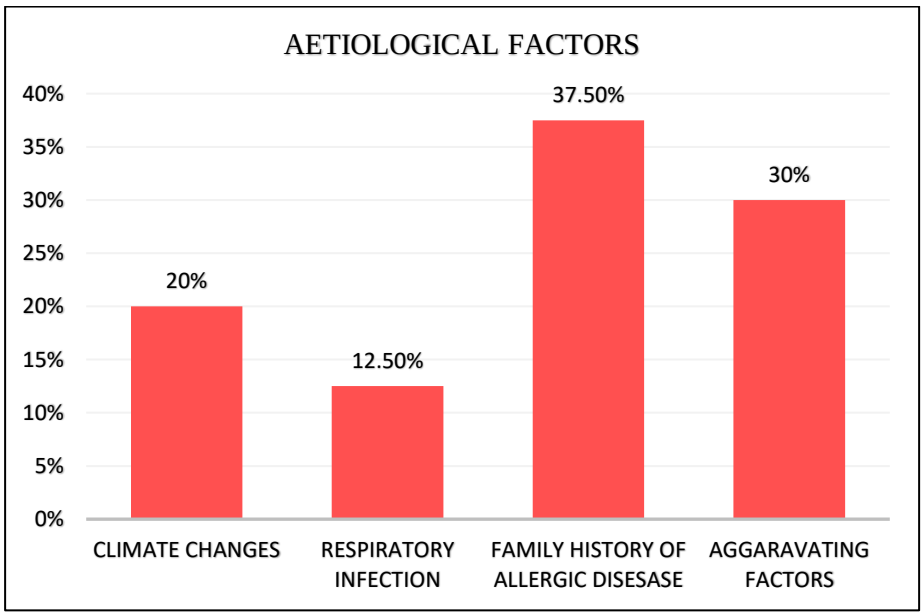


INFERENCE:

Vaathaneer, Pithaneer was observed in 10% of cases and Kabaneer was observed in 80% of cases.

12.AETIOLOGICAL FACTORS OF SOOLI KANAM:

S.NO	AETIOLOGICAL FACTOR	NO OF CASES	PERCENTAGE
1	CLIMATIC CHANGES	8	20%
2	RESPIRATORY INFECTION	5	12.5%
3	FAMILY H/O OF ALLERGIC DISEASES	15	37.5%
4	AGGRAVATED FACTORS LIKE INHALED ALLERGENS, COOL BEVERAGES & ICE CREAMS	12	30%

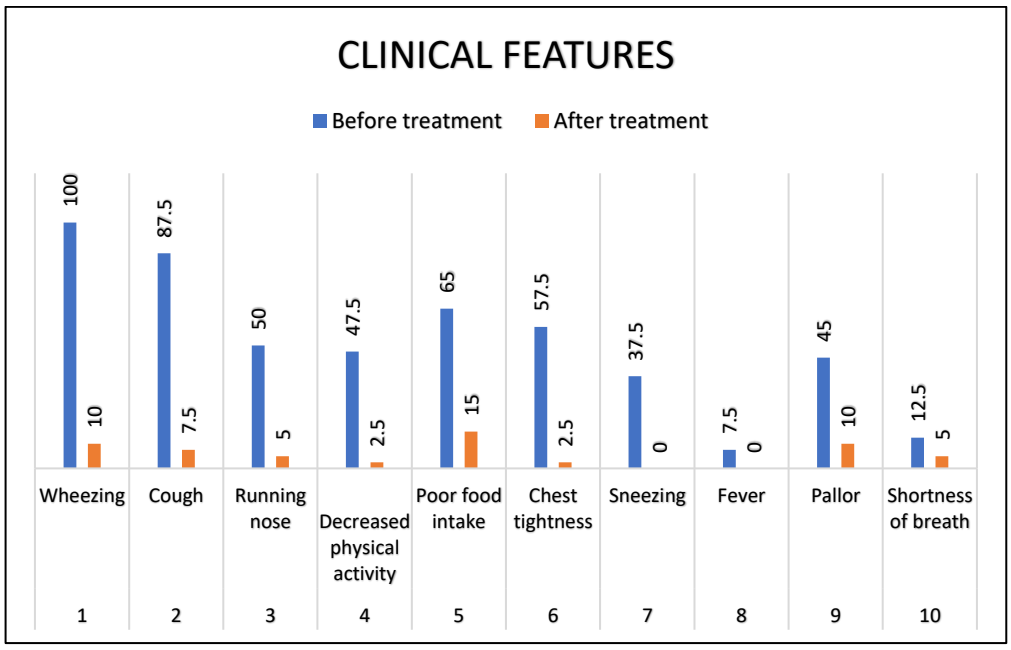


INFERENCE:

From the above table the climate changes are about 20%. 12.5% of cases have a respiratory infection. 30%of cases have Aggravating factors like inhaled allergens, cool beverage & ice creams and 37.5% of cases have Family history of allergic diseases. Hence it is evident that positive family h/o is one among the main cause for soolikanam.

13.CLINICAL FEATURES:

S.NO	CLINICAL FEATURES	BEFORE TREATMENT		AFTER TREATMENT	
		NO.OF CASES	PERCENTAGE	NO.OF CASES	PERCENTAGE
1	WHEEZING	40	100%	4	10%
2	COUGH	35	87.5%	3	7.5%
3	RUNNING NOSE	20	50%	2	5%
4	CHEST THIGHTNESS	23	57.5%	1	2.5%
5	DECREASED PHYSICAL ACTIVITIES	19	47.5%	1	2.5%
6	POOR INTAKE	26	65%	6	15%
ASSOCIATED SYMPTOMS					
7	SNEEZING	15	37.5%	0	0
8	FEVER	3	7.5%	0	0
9	PALLOR	18	45%	4	10%
10	SHORTNESS OF BREATHE	5	12.5%	2	5%

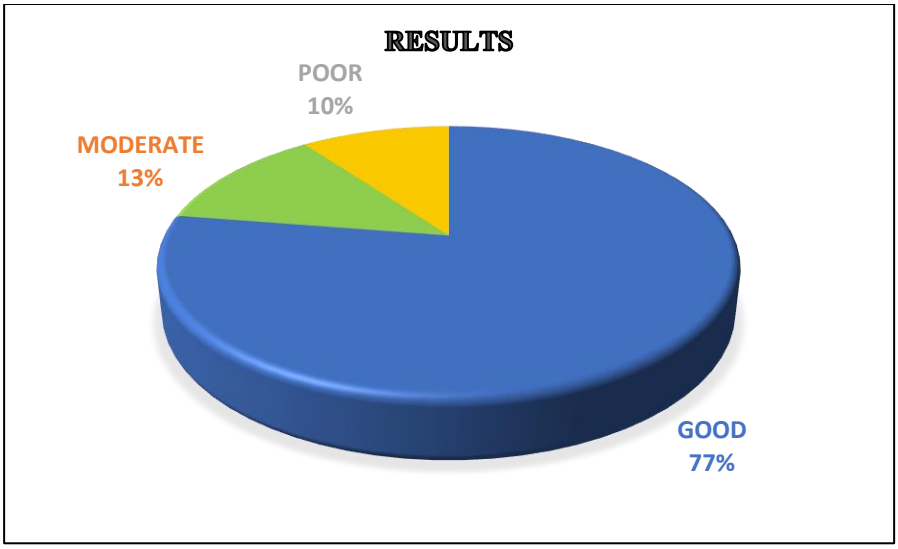


INFERENCE:

Major clinical symptoms reported to be Wheezing (100%) after treatment it was reduced to 10%. 87.5% of cases had cough before treatment, after treatment it was reduced to 7.5%. 50% of cases had running nose, it was reduced to 5%.47.5% of cases had decreased p hysical activity, it was reduced to 2.5%. 65% of cases had poor diet intake, it was reduced to 15%. 57.5% 0f cases had chest tightness, it was reduced to 2.5% & and most of other clinical signs were relieved after treatment

14.RESULTS:

S.NO	RESULTS	NO OF CASES	PERCENTAGE
1	GOOD	31	77
2	MODERATE	5	13
3	POOR	4	10



INFERENCE:

77% of cases showed good results and 13% of cases showed moderate response, 10% of cases showed poor response, these results are based on the clinical improvement.

Parameter for assessment of bronchial asthma:

The clinical assessment of asthma was carried out on the basis of modified asthma scale.

SI No	Parameters	Scores			
1	Breathelessness	Mild (1)	Moderate (2)	Severe (3)	Absent (0)
2	Talks in	Comphrehensively (1)	Phrases (2)	Words (3)	Talk normally (0)
3	Accessory muscles	Nil or minimal (1)	Chest indrawing (2)	Chest indrawing, flaring up of alae nasi (3)	Absent (0)
4	Wheeze	Audible during Expiratory phase with stethoscope (1)	Audible during both phases of respiration with stethoscope (2)	Audible in both phase of Respiration without stethoscope (3)	Not audible or absent with normal air entry (0)
5	Pulse/min	<100 (1)	100-200 (2)	>120 (3)	Normal (0)
6	Sensorium	Anxious (1)	May be agitated (2)	Agitated (3)	Normal (0)
7	Symptoms	≤2/weeks (1)	>2/weeks (2)	Continues (3)	Abesnt (0)

Minimum score – 0 & Maximum score is 21

0 – Normal, 1 – 7 Mild, 8 – 14 Moderate, 15 – 24 Severe

Modified scoring system (GINA.,2002, Ghai o.p.,2004 & IAP,1999).

S.No	OP.NO	AGE/SEX	TOTAL SCORES	
			BEFORE TREATMENT	AFTER TREATMENT
1	8402	8/FC	12	0
2	7517	10/FC	15	8
3	8512	12/MC	14	0
4	9593	10/MC	7	0
5	1568	12/MC	15	4
6	3159	10/MC	7	0
7	2953	3/MC	9	0
8	9594	7/FC	7	0
9	4257	5/FC	15	0
10	4620	6/MC	12	0
11	4762	12/MC	8	0
12	5517	5/FC	8	0
13	5805	8/MC	9	0
14	5945	4/MC	16	0
15	6063	10/MC	14	0
16	6798	11/MC	8	0
17	7089	7/MC	13	2
18	7315	5/FC	10	0
19	7675	5/MC	8	0

20	**7495**	**8/MC**	**8**	**0**
21	**1737**	**11/FC**	**11**	**2**
22	**5242**	**4/MC**	**9**	**0**
23	**5224**	**9/FC**	**8**	**0**
24	**6340**	**7/MC**	**17**	**0**
25	**6847**	**10/MC**	**8**	**0**
26	**7043**	**6/FC**	**24**	**10**
27	**8052**	**8/MC**	**7**	**0**
28	**8051**	**9/MC**	**11**	**4**
29	**9080**	**4/MC**	**13**	**6**
30	**9105**	**4/FC**	**9**	**0**
31	**9118**	**7/MC**	**14**	**0**
32	**594**	**3/FC**	**16**	**0**
33	**1683**	**3/MC**	**11**	**5**
34	**3229**	**8/FC**	**9**	**0**
35	**3827**	**3/MC**	**12**	**2**
36	**3607**	**7/MC**	**11**	**1**
37	**3973**	**12/MC**	**11**	**0**
38	**4336**	**10/FC**	**7**	**0**
39	**4662**	**6/MC**	**11**	**0**
40	**7603**	**3/MC**	**7**	**0**

MC- Male child FC- Female child

OUT PATIENTS RECORD

S.NO	OP.NO	NAME	AGE/ SEX	TREATMENT STARTED DATE	REMARKS
1	8402	Nithila	8/FC	09.10.18	Good
2	7517	Varshini	10/FC	03.12.18	Good
3	8512	Arun	12/MC	05.12.18	Good
4	9593	Nareshkumar	10/MC	08.12.18	Poor
5	1568	Mohan	12/MC	13.12.18	Good
6	3159	Karthikeyan	10/MC	14.12.18	Good
7	2953	Hariharasudan	3/MC	17.12.18	Good
8	9594	Idhayasri	7/FC	18.12.18	Good
9	4257	Ananya	5/FC	21.12.18	Moderate
10	4620	Rithikeshwaren	6/MC	22.12.18	Good
11	4762	Ashwagh	12/MC	22.12.18	Good
12	5517	Gowsalya	5/FC	24.12.18	Moderate
13	5805	Lingesh	8/MC	25.12.18	Good
14	5945	Saran	4/MC	26.12.18	Good
15	6063	Danush	10/MC	26.12.18	Good
16	6798	Aathil	11/MC	27.12.18	Good
17	7089	Varun	7/MC	28.12.18	Poor
18	7315	Mokshitha	5/FC	28.12.18	Good
19	7675	Dakshan	5/MC	29.12.18	Good
20	7495	Ganesh	8/MC	29.12.18	Good
21	1737	Kayalvizhi	11/FC	10.01.19	Good
22	5242	Hemanth kumar	4/MC	23.01.19	Moderate
23	5224	Fathu muthu	9/FC	23.01.19	Good
24	6340	Thaveesh	7/MC	26.01.19	Good
25	6847	Dhanush	10/MC	28.01.19	Good
26	7043	Meganethra	6/FC	28.01.19	Good

27	**8052**	**Sagar**	**8/MC**	**30.01.19**	**Good**
28	**8051**	**Syed afrose**	**9/MC**	**30.01.19**	**Poor**
29	**9080**	**Vinith**	**4/MC**	**02.02.19**	**Moderate**
30	**9105**	**Lafitha**	**4/FC**	**02.02.19**	**Good**
31	**9118**	**Aakash**	**7/MC**	**02.02.19**	**Good**
32	**594**	**Kanishka**	**3/FC**	**06.02.19**	**Good**
33	**1683**	**Rushan shiva**	**3/MC**	**09.02.19**	**Good**
34	**3229**	**Priya**	**8/FC**	**14.02.19**	**Good**
35	**3827**	**Mithran**	**3/MC**	**15.02.19**	**Poor**
36	**3607**	**Ramesh**	**7/MC**	**15.02.19**	**Good**
37	**3973**	**Sheshan**	**12/MC**	**16.02.19**	**Moderate**
38	**4336**	**Lathika**	**10/FC**	**17.02.19**	**Good**
39	**4662**	**Vishnu**	**6/MC**	**18.02.19**	**Good**
40	**7603**	**Kishore**	**3/MC**	**26.02.19**	**Good**

INVESTIGATION REPORT OF THE PATIENT
(BLOOD INVESTIGATION)

S.NO	OP NO	AGE/ SEX	HAEMATOLOGICAL REPORT															
			BT				AT				AEC		ESR				Hb	
											BT	AT	BT		AT		BT	AT
			TC	P%	L%	E%	TC	P%	L%	E%			½Hrs	1Hrs	½Hrs	1Hrs		
1	8402	8/FC	5100	40	50	10	6800	50	46	6	510	408	14	22	5	15	10	12.1
2	7517	10/FC	10400	70	25	5	11500	64	32	4	520	460	5	15	3	8	13.5	13
3	8512	12/MC	6750	47	43	10	12000	54	40	6	675	720	7	18	3	8	13.3	12
4	9593	10/MC	9800	62	33	5	12000	66	31	3	490	360	16	25	8	10	12.7	13
5	1568	12/MC	5100	58	33	9	7500	60	35	5	495	375	20	38	10	15	11.2	13
6	3159	10/MC	9800	60	35	5	11000	64	34	3	490	330	18	36	12	24	13	13
7	2953	3/MC	5400	52	39	9	9000	59	37	4	486	360	5	15	5	10	13.2	13
8	9594	7/FC	6500	65	30	9	10500	64	33	3	585	315	15	25	10	20	12.6	12
9	4257	5/FC	8500	47	46	7	9000	55	40	5	595	450	5	16	5	10	11.8	12
10	4620	6/MC	5400	65	27	8	12000	63	35	2	432	240	3	5	5	10	13.7	14
11	4762	12/MC	9900	65	31	4	10200	69	30	1	396	120	4	10	2	4	14.7	14
12	5517	5/FC	5800	56	34	10	10500	60	36	4	580	420	15	35	10	20	9.7	12
13	5805	8/MC	4400	51	39	10	5100	59	39	6	440	306	5	15	5	10	11.4	13
14	5945	4/MC	5400	55	38	7	10000	64	34	2	378	200	5	12	4	8	12.5	13

15	6063	10/MC	7600	55	36	9	9500	54	41	5	684	475	7	8	5	10	12.3	12
16	6798	11/MC	5400	46	46	8	8500	68	30	4	432	340	5	15	5	9	12.8	13
17	7089	7/MC	9030	46	47	7	9300	60	35	5	632	465	26	42	8	16	12.3	13
18	7315	5/FC	8100	52	42	6	8000	60	38	4	486	392	4	7	5	10	12.1	12
19	7675	5/MC	6510	64	28	8	11500	60	35	5	520	575	7	18	5	10	12.3	13.5
20	7495	8/MC	9300	56	39	5	11100	60	38	3	465	333	4	10	5	10	13.5	13.5
21	1737	11/FC	6100	68	26	6	6100	61	35	4	366	244	13	22	5	8	12.7	11.3
22	5242	4/MC	6300	40	51	9	9000	60	35	5	567	450	7	8	5	10	11.5	12
23	5224	9/FC	4800	44	48	8	9800	65	33	2	384	294	15	26	10	20	12.1	13
24	6340	7/MC	9500	67	27	6	10900	68	38	4	570	436	2	5	5	10	14.5	13.5
25	6847	10/MC	7600	55	36	9	6000	60	38	2	684	120	7	18	5	10	12	13
26	7043	6/FC	11700	74	21	5	10500	65	38	4	585	420	7	15	5	10	13	12
27	8052	8/MC	6500	58	34	8	8500	65	33	4	520	340	4	12	5	10	11.6	13
28	8051	9/MC	8500	56	37	7	8000	64	35	6	595	505	6	12	5	10	13	12
29	9080	4/MC	5900	40	51	9	10400	65	33	4	531	416	5	15	3	12	10.5	12
30	9105	4/FC	6500	37	33	8	9000	60	38	5	520	450	5	15	4	8	13.1	12
31	9118	7/MC	9100	61	33	6	9000	60	36	4	546	360	5	12	4	8	11.9	12
32	594	3/FC	11600	65	30	5	14000	65	33	3	580	420	15	25	5	10	13.2	14
33	1683	3/MC	6900	59	36	5	6700	66	32	3	345	201	9	20	7	14	12.1	13.1

34	**3229**	**8/FC**	**11500**	**68**	**28**	**4**	**11300**	**64**	**34**	**3**	**460**	**339**	**18**	**36**	**5**	**10**	**12.3**	**13**
35	**3827**	**3/MC**	**8800**	**47**	**47**	**6**	**8000**	**65**	**33**	**4**	**528**	**320**	**3**	**10**	**5**	**10**	**11.1**	**12**
36	**3607**	**7/MC**	**8500**	**60**	**32**	**8**	**9000**	**65**	**33**	**5**	**680**	**450**	**15**	**30**	**10**	**20**	**12**	**13.1**
37	**3973**	**12/MC**	**4500**	**64**	**31**	**8**	**11000**	**66**	**32**	**3**	**360**	**303**	**8**	**18**	**5**	**10**	**13**	**13**
38	**4336**	**10/FC**	**7500**	**62**	**28**	**10**	**12000**	**64**	**34**	**6**	**750**	**720**	**18**	**36**	**10**	**20**	**11.6**	**12**
39	**4662**	**6/MC**	**8400**	**71**	**25**	**4**	**8000**	**70**	**28**	**4**	**336**	**320**	**13**	**22**	**10**	**20**	**12**	**13**
40	**7603**	**3/MC**	**9200**	**65**	**29**	**6**	**11000**	**64**	**34**	**4**	**552**	**440**	**7**	**15**	**5**	**10**	**8.9**	**9**

BT - Before Treatment; AT - After Treatment; P - Polymorphs; L - Lymphocytes; E - Eosinophils; AEC - Absolute Eosinophil count; ESR - Erthrocyte sedimentation Rate; Hb - Haemoglobin.

INVESTIGATION REPORT OF THE PATIENTS

(URINE INESTIGATION)

S.NO	OP.NO	NAME	AGE/ SEX	URINE ANALYSIS					
				BEFORE TREATMENT			AFTER TREATMENT		
				Alb	Sug	Dep	Alb	Sug	Dep
1	8402	Nithila	8/FC	NIL	NIL	NAD	NIL	NIL	NAD
2	7517	Varshini	10/FC	NIL	NIL	NAD	NIL	NIL	NAD
3	8512	Arun	12/MC	NIL	NIL	NAD	NIL	NIL	NAD
4	9593	Naresh kumar	10/MC	NIL	NIL	NAD	NIL	NIL	NAD
5	1568	Mohan	12/MC	NIL	NIL	NAD	NIL	NIL	NAD
6	3159	Karthikeyan	10/MC	NIL	NIL	NAD	NIL	NIL	NAD
7	2953	Harihara sudan	3/MC	NIL	NIL	NAD	NIL	NIL	NAD
8	9594	Idhayasri	7/FC	NIL	NIL	NAD	NIL	NIL	NAD
9	4257	Ananya	5/FC	NIL	NIL	NAD	NIL	NIL	NAD
10	4620	Rithikeshwaren	6/MC	NIL	NIL	NAD	NIL	NIL	NAD
11	4762	Ashwagh	12/MC	NIL	NIL	NAD	NIL	NIL	NAD
12	5517	Gowsalya	5/FC	NIL	NIL	NAD	NIL	NIL	NAD
13	5805	Lingesh	8/MC	NIL	NIL	NAD	NIL	NIL	NAD
14	5945	Saran	4/MC	NIL	NIL	NAD	NIL	NIL	NAD
15	6063	Danush	10/MC	NIL	NIL	NAD	NIL	NIL	NAD
16	6798	Aathil	11/MC	NIL	NIL	NAD	NIL	NIL	NAD
17	7089	Varun	7/MC	NIL	NIL	NAD	NIL	NIL	NAD
18	7315	Mokshitha	5/FC	NIL	NIL	NAD	NIL	NIL	NAD
19	7675	Dakshan	5/MC	NIL	NIL	NAD	NIL	NIL	NAD
20	7495	Ganesh	8/MC	NIL	NIL	NAD	NIL	NIL	NAD
21	1737	Kayalvizhi	11/FC	NIL	NIL	NAD	NIL	NIL	NAD
22	5242	Hemanthkumar	4/MC	NIL	NIL	NAD	NIL	NIL	NAD
23	5224	Fathu muthu	9/FC	NIL	NIL	NAD	NIL	NIL	NAD

24	6340	Thaveesh	7/MC	NIL	NIL	NAD	NIL	NIL	NAD
25	6847	Dhanush	10/MC	NIL	NIL	NAD	NIL	NIL	NAD
26	7043	Meganethra	6/FC	NIL	NIL	NAD	NIL	NIL	NAD
27	8052	Sagar	8/MC	NIL	NIL	NAD	NIL	NIL	NAD
28	8051	Syed afrose	9/MC	NIL	NIL	NAD	NIL	NIL	NAD
29	9080	Vinith	4/MC	NIL	NIL	NAD	NIL	NIL	NAD
30	9105	Lafitha	4/FC	NIL	NIL	NAD	NIL	NIL	NAD
31	9118	Aakash	7/MC	NIL	NIL	NAD	NIL	NIL	NAD
32	594	Kanishka	3/FC	NIL	NIL	NAD	NIL	NIL	NAD
33	1683	Rushan shiva	3/MC	NIL	NIL	NAD	NIL	NIL	NAD
34	3229	Priya	8/FC	NIL	NIL	NAD	NIL	NIL	NAD
35	3827	Mithran	3/MC	NIL	NIL	NAD	NIL	NIL	NAD
36	3607	Ramesh	7/MC	NIL	NIL	NAD	NIL	NIL	NAD
37	3973	Sheshan	12/MC	NIL	NIL	NAD	NIL	NIL	NAD
38	4336	Lathika	10/FC	NIL	NIL	NAD	NIL	NIL	NAD
39	4662	Vishnu	6/MC	NIL	NIL	NAD	NIL	NIL	NAD
40	7603	Kishore	3/MC	NIL	NIL	NAD	NIL	NIL	NAD

Alb – Albumin Sug – Sugar ; Dep – Deposit ; NAD – No abnormal Deposits

DISCUSSION

Sooli kanam is a pediatric disease, the clinical features of which are clearly described in various Siddha literatures. This disease most probably correlates with childhood bronchial asthma

In this study 40 cases were treated at the post graduate Kuzhathai maruthuvam department. Siddha methods of diagnosis were carried out and recorded in the selection proforma, and the diagnosis was confirmed with the help of modern investigations. The patients were treated with the drug " Kana Nei " are clearly observed. The observations are discussed here under,

1. DISTRIBUTION ACCORDING TO AGE:

This study indicates that children under the age group of 7 to 10 years 42.5% are mostly affected.

27.5% children are affected in the age group of 4 to 6 years.

17.5% children are affected in the age group of 1 to 3years.

12.5% children are affected in the age group of 11 to 12 years

2. DISTRIBUTION ACCORDING TO SEX:

Among 40 cases, 27 cases (67.5%)were male children and 13 cases (32.5%) were female children.

3.DISTRIBUTION ACCORDING RELIGION:

Among 40 cases 87.5% were Hindu.

10% were Muslims.

10% were Christian.

4. FAMILY HISTORY:

According to family history 57.5% of the cases had positive family history and 42.5% of the cases had no relevant family history. The highest incidence of cases had positive family history.

5. DIET HISTORY:

According to diet history high incidence of cases (70%) was noted in mixed diet and in vegetarian (30%) cases were noted.

6. DISTRIBUTION ACCORDING TO SOCIO ECONOMIC STATUS:

Among 40 cases, maximum numbers of patients 50% were in low income group, 35% were in middle income group and 15% were in high income group.

The highest incidence occurred in low income group. Because of poverty, malnutrition and unhygienic this disease is more prevalent among the poor.

7. DISTRIBUTION ACCORDING TO PARUVA KAALANGAL :

Among the 40 cases, highest incidence 77.5% cases were observed in Munpani kaalam, 10% cases were observed in Pinpani kaalam and koothir kalam, 2.5% of cases were observed in Kaar kaalam.

8. UYIR THATHUKKAL – VATHAM:

In vatham, all cases had affected in Pranan, Uthanan, Samanan and Kirukiran (100%). Viyanan and Naagan was affected in 37.5%, Devathathan was affected in 25%, Abanan was affected in 7.5%.

UYIR THATHUKKAL – PITHAM:

In pitham, Anilam was affected in 67.5% of cases.

45% of cases had affected in Ranjagam,

72.5% of cases had affected in Saathagam.

Pirasagam was affected in 10% of cases.

UYIR THATHUKKAL – KABAM:

In Kabam, Avalambagam was affected in all patients (100%).

Kilethagam was affected in 75% of patients.

9. 7 UDAL KATTUKAL:

Out of 40 cases 100% of the cases had affected in saaram.

50% of cases had affected in senneer and kozuppu

37.5 of cases had affected in oon.

10. ENVAGAI THERVUGAL:

According to the study Naa and Sparisam were affected in 45% of cases.

mozhi affected in 25% of cases.

Niram affected in 10% of cases.

Vatha kabam affected in 75% of cases.

Kaba pitham affected in 20% of cases.

Pitha kabam affected in 5% of cases.

11. NEIKURI :

Among 40 cases Kaba neer was observed in 80% of cases.

Vaatha neer, Pitha neer was observed in 10% of cases.

12. AETIOLOGICAL FACTORS OF SOOLI KANAM :

Among the 40 cases 20% was caused by climatic changes.

12.5% of cases have a respiratory infection.

30% of cases have Aggravating factors like inhaled allergens, cool beverage & ice creams.

37.5% of cases have Family history of allergic diseases.

13. CLINICAL FEATURES:

Major clinical symptoms reported to be Wheezing (100%) after treatment it was reduced to 10%. 87.5% of cases had cough before treatment, after treatment it was reduced to 7.5%. 50% of cases had running nose, it was reduced to 5%. 47.5% of cases had decreased physical activity, it was reduced to 2.5%. 65% of cases had poor diet intake, it was reduced to 15%. 57.5% 0f cases had chest tightness, it was reduced to 2.5% & and most of other clinical signs were relieved after treatment.

14. LAB INVESTIGATIONS:

Routine examination of blood and urine were done before and after treatment.

In most of the cases (100%) elevated ESR and Absolute Eosinophil count was decreased after treatment (90%).

15. BIOCHEMICAL ANALYSIS:

Bio chemical analysis shows

Acid Radicals- Chlroide

Basic Radicals- Iron, Calcium, Starch, Reducing sugar are presents.

16. PHARMACOLOGICAL ACTIVITY:

Pharmacological analysis showed the drug has significant Bronchodilator activity.

17. PHYSICO CHEMICAL ANALYSIS:

Viscosity at 50^{o} c (Pa s)	- 54.62
Refractive index	- 1.44
Weight per ml (gm/ ml)	- 0.073 gm/ml
Iodine value (mg 12/g)	- 97.155

Saponification value (mg - 194.56

Of KOH to saponify 1gm of fat)

Acid value mg KOH/ g - 0.5049

Peroxidase value mEq/kg - 4.063

18. TOXICITY STUDY OF THE DRUG:

The acute and sub-acute toxicity study of the trial drug was carried out in Wistar albino rats reveals that the drug has no adverse effects, of it is safe to human being

19. RESULT:

Satisfactory improvement was reported in 21 days of commencement of treatment. Out of 40 cases, 31 cases (77%) showed Good response and also remarkable relief of signs and symptoms.

Moderate result was observed in 5 cases (13%) with reduction of signs and symptoms. In cases the result was poor 4 (10%) a there is no significant improvement of symptoms.

20. STATISTICAL REPORT:

Since the p value is significant in all clinical features and also in absolute eosinophil count, So there is significant reducing of Absolute eosinophil count & clinical features among the patients for the treatment of Sooli Kanam (Childhood Bronchial asthma). Hence it is concluded that the treatment was effective and significant.

SUMMARY

1. The aim of the study is to assess the efficacy of trial drug **"KANA NEI"** for **"SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA)"** without any adverse effects.

2. The etiology, pathogenesis, signs and symptoms of Sooli kanam have been correlated with that of childhood bronchial asthma with evidence of literature.

3. Clinical diagnosis and selection of cases based on clinical features described in Balavaagadam text book and also using questionnaire.

4. The internal medicine chosen for treatment and management of Sooli kanam was Kana nei 1g 3 -5 yrs & 2gm 6-12 yrs, twice a day, after food.

5. The trial drug selection based on its siddha pharmacological action to pacify the deranged vatham, pitham and kabam and also due to its, Bronchodilator and Anti histamine effect of the ingredients.

6. 40 cases were diagnosed with Sooli kanam clinically observed for clinical diagnosis, laboratory diagnosis, Absolute eosinophil count during the treatment and the results were dealt in the proforma.

7. Laboratory diagnosis was done by modern methods of examinations.

8. The treatment covers administration of trial drug according to the age and also includes pranayamam.

9. The documentation of observation made during the clinical study showed that the drug is clinically more effective.

10. The biochemical analysis Shows Acid Radicals- chloride and Basic Radicals- Iron, Calcium, Starch, Reducing sugar are present.

11. Sterility test by pour plate method of Kana nei shows no growth / colonies like E-coli, Salmonella, Staphylococcus Aureus and Pseudomonas Aeruginosa.

12. In the pharmacological analysis, the trial drug Kana Nei had significant, Bronchodilator activity which controlling the airway hyper responsiveness help to improve the patients quality of life.

13. The physico chemical analysis of the trial drug shows the Viscosity at 50^{o} c (Pa s) - 54.6, Refractive index -1.44,Weight per ml (gm/ ml) -0.073 gm/ml, Iodine value (mg 12/g) - 97.155, Saponification value (mg of KOH to saponify 1gm of fat) - 194.56, Acid value mg KOH/ g - 0.5049, Peroxidase value mEq/kg - 4.063 , So it shows the safe and effectiveness of the drug. With these benefits of **KANA NEI** is more effective drug for **SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA).**

CONCLUSION

Bronchial asthma is the most common chronic disabling disease of childhood as measured by school absences, emergency department visits and hospitalizations.

Asthma is the leading chronic disease among children in most industrialized countries, Growing at an alarming rate, there is evidence that its prevalence has increased considerably over the past 20 years, especially in children. Its impact in reducing the quality of life in children.

In this clinical study Kana Nei were taken as Internal medicine respectively. Sooli kanam (Bronchial asthma) occurs due to alteration in Kaba kutram. In Kana Nei most of the drugs have Kaarpu suvai, and it decrease the Kaba kuttram. Ghee based medicine nourishes the immune system and it increases appetite, overall helps to improve the Health. So I choose this drug and it is more effective to reduce the Kaba kuttram in Bronchial asthma.

The treatment of Sooli kanam with Kana Nei has showed Good response with no adverse effect and ensure to be safe, effective and simple to administration. The drugs have Bronchodilator activity.

Statistically it is concluded that the treatment was effective and highly significant

By using Scores, parameters for assessment of Bronchial asthma shows there is a significant difference between Before Treatment and After Treatment..

Clinical results were found to be good improvement was found in 77 % of cases, moderate in 13% of cases and Poor in 10% of cases.

The clinical trial conducted in selected patients was satisfactory and encouraging.

BIO STATISTIC REPORT

TREATMENT FOR SOOLI KANAM (CHILHOOD BRONCHIAL ASTHMA):

The most popular non parametric statistical tool namely, Paired Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

Table 1:

Results of Statistical Analysis of subjective parameters observed Before and Afetr Treatment of 40 (n) patients of Sooli Kanam at Arignar Anna Hospital, Chennai- 106

S.NO	Clinical features	No of cases	Before Treatment n%	No of cases	After Treatment n%	P Value
1	Wheezing	40	100%	4	10%	P<0.000
2	Cough	35	87.5%	3	7.5%	P<0.000
3	Running nose	20	50%	2	5%	P<0.000
4	Chest tightness	23	57.5%	1	2.5%	P<0.000
5	Decreased physical activities	19	47.5%	1	2.55	P<0.000
6	Poor intake	26	65%	6	15%	P<0.000
7	Sneezing	15	37.5%	0	0	P<0.000

8	Fever	3	7.5%	0	0	P<0.000
9	Pallor	18	45%	4	10%	P<0.000
10	Shortness of breathe	5	12.5%	2	5%	P<0.070

Paired t test, C.I : 95% p<0.01

Software : spss 21 version

Number of cases: 40

Inferance:

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of sooli kanam (childhood Bronchial asthma). Hence it is concluded that the treatment was Effective and Significant.

Table 2:

Results of Statistical Analysis of Objective parameters observed Before and After treatment of 40 (n) patients of Sooli Kanam at Arignar Anna Hospital, Chennai-106.

S.no	Parameters	Mean		Difference	Paired t value	p value	Statistical significance of difference
		Before treatment	After Treatment				
1	AEC	518	379	138.95	8.958	P<0.000	Significant

The Minimum value of Absolute eosinophil count is 336 before Treatment and after the intervention of the Kana Nei it was Reduced to 120. The Maximum value was Reduced from 750 to 720.

Since the p value is <0.001, there is a significant difference between Before Treatment and After Treatment values. After the Intervention of Kana Nei, the mean of the Absolute eosinophil count is Decreased about 138.95

The above findings (ie) Both the Clinical features and the Absolute eosinophil count shows that the P value is <0.001, hence **we can reject the Null hypothesis** and the above said results shows that there is a significant evidence seen in both the Clinical symptoms and Absolute eosinophil counts are decreased after the intervention of the Kana Nei. It shows that the drug **Kana Nei** is Highly significant for the Treatment of **SOOLI KANAM (Childhood Bronchial Asthma).**

NULL HYPOTHESIS: There is no difference between the Two dependent group (Before and After Treatment).

ALTERNATIVE HYPOTHESIS: There is a difference between the Two dependent group (Before and After Treatment).

The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....D. JEEVITHA.....

For participating as Resource Person / Delegate in the Twenty Fourth Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 24th to 28th April 2017.

Dr.N.KABILAN, M.D.(S),Ph.D.,
PROF & HEAD DEPT.OF SIDDHA

Prof.**Dr.T.BALASUBRAMANIAN,** M.D.,D.L,O.,
REGISTRAR

Prof.**Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-2/017/2017

Protocol title: AN OPEN CLINICAL STUDY ON SOOLIKANAM (BRONCHIAL ASTHMA) IN CHILDRENTO EVALUATE THE EFFICACY OF SIDDHA TRIAL DRUG KANA NEI
Principal Investigator: Dr.D.JEEVITHA
Name & Address ofInstitution: Government Siddha Medical College, Arumbakkam, Chennai-106
☑ New Review ☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY): 06-04-2017 Date of Previous Review, If Revised Application:
Decision of the IEC ☐ Recommended ☑ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions / Reasons / Remarks: 1.Change Dosage: 2-5yrs:1gm(Bd), 6-12yrs: 2gm(Bd) 2.Pneumonia added in Exclusion criteria. 3.Added Score.
Recommended for a period of 1 year fromdate of completion of preclinical studies :

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

Dr.P.Jeyaprakashnarayanan
Chairman

6.4.17
Dr.K.Kanakavalli
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date : 06.04.2017
Sub : IEC Review of research proposals
Ref : Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
Dr.P JEYAPRAKASH NARAYANAN. M.D(S)., Chairman	✓	
Dr. K. KANAKAVALLI., MD(S)., Member secretary	✓	6.4.17
Dr.SATHYA RAJESWARAN M.D(S), Clinician - Siddha	✓	6/4/17
Dr.KABILAN M.D(S), Clinician - Siddha	✓	6/4/17
Dr.R.VASUDEVAN, M.D(S)., PG.DIP (Clinical research), Msc (Medical sociology), Sociologist	✓	6/4/17
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Mr.B.PADMANABHA PILLAI, Philosopher		
Mrs. PREETHA SARAVANAN, Public person		

Dr.P.Jeya prakash narayanan M.D(s).,
Chairman

6.4.17
Dr.K.Kanakavalli, M.D(s)
Member secretary

Government Siddha Medical College
Department of Medicinal Botany

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,
Asst. Professor
Head of the Department

6, Anna Arch Rd,
NSK Nagar,
Arumbakkam, Chennai,
Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given to Dr. D. Jeevitha B.S.M.S. doing M.D. (S) in Department of Kuzhanthai maruthuvam at Government Siddha Medical College, Arumbakkam, Chennai-106 is identified below as

S.NO	DRUG NAME	BOTANICAL NAME	FAMILY NAME
1	PARUTHIVITHAI PARUPU	*GOSSYPIUM HERBACEUM*	MALVACEAE
2	PODUTHALAI KAAI	*PHYLA NODIFERA*	VERBENACEAE
3	KIRAMBU	*SYZYGIUM AROMATICUM*	MYRTACEAE
4	KICHILI KIZHANGU	*CURCUMA ZEDOARIA*	ZINGIBERACEAE
5	SEERAGAM	*CUMINUM CYMINUM*	APIACEAE
6	ELAVANGA PATTAI	*CINNAMOMUM VERUM*	LAURACEAE
7	ELAVAM PISIN	*BOMBAX MALABARICUM*	BOMBACACEAE
8	JAATHI KAAI	*MYRISTICA FRAGRANS*	MYRISTICACEAE
9	KAAICHUKATTI	*CATECHULOZENGES*	FABACEAE
10	COW GHEE	---	----

References: Flora of Presidency, Gamble, J. S

Date: 05.04.2018

Place: Chennai

5/4/2018

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,

Head
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(Medicinal Botany and Pharmacognosy)
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Old Mahabalipuram Road,
Thoraipakkam, Chennai - 600 097.

ISO 9001 : 2008
Reg. No : RQ91/3038

Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai.
Approved by Pharmacy Council of India, New Delhi, and
All India Council for Technical Education, New Delhi

CERTIFICATE

This is to certify that the project title "An open clinical study on SOOLI KANAM (BRONCHIAL ASTHMA) in children with the evaluation of Siddha trial drug KANA NEI for its toxicological, BRONCHODILATOR activity in Wistar albino rats" has been approved by IAEC

IAEC No: LV/10/CLBMCP/2018

C.L. Baid Metha College of Pharmacy ★ CHENNAI-97 ★ Thoraipakkam

Dr.P.Muralidharan

International Conference on

"Sports Medicine, Yoga, Fitness Therapy & Rehabilitation"

SYFTR-2019

Date: 11th and 12th March 2019

CERTIFICATE

This is to certify that Mr/Ms/Dr/Prof D. JEEVITHA, GSMC has participated/Chaired a session in the International conference, organized by Research and Development wing, Sree Balaji Medical College & Hospital, Chromepet, Chennai, Tamil Nadu, India. He/she has presented a Paper entitled on _____ and the CME Points Awarded _____

Prof . S. Benjamin Prakash
German University of Physical Education & Sports Sciences Cologne,Germany

Prof. Senthamil R. Selvan
Principal Scientist, Biomarker Strategies Rockville, MD,USA

Prof.W.M.S. Johnson
Dean -Incharge
SBMCH

Prof. P. Ramasamy
Director -Research
SBMCH

Central Council for Research in Siddha (CCRS)

MANIPAL UNIVERSITY

Central Council for Research in Siddha (CCRS), Ministry of AYUSH, Govt. of India, Arumbakkam, Chennai-600106
Centre for Integrative Medicine and Research (CIMR), Manipal University
Department of Pharmacology, Melaka Manipal Medical College, Manipal University

CERTIFICATE

This is to certify that Dr./Mr./Ms D. Jeevitha, GSMC, Chennai

presented a poster in the Seminar cum Workshop on "Management of dermatological disorders and cancer —moving towards an integrative (Siddha & Modern) approach" held during 11-12 February 2017 at Manipal University, Manipal - 576104.

Dr. Vishaal Bhat
Coordinator
CIMR, MU

Dr. Vasudha Devi
Head, Dept. of Pharmacology
MMMC, MU

Prof. Dr. R. S. Ramaswamy
Director General
CCRS, Chennai

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E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 – 42691289
Website: www.nobleresearchsolutions.com

Name and Address of the Researcher	**Dr.D.Jeevitha** **Government Siddha Medical College,** **Chennai, Tamil Nadu, India**
Sample –ID	**Kana Nei - KAN**
Parameter Requested for Analysis	**Phytochemical Analysis**
Sample Received	**In Person**
Method of Analysis	**PLIM- Protocol – ASU Formulations**
Analysis Type	**Physicochemical Analysis**
Result of Analysis	**Test and Analytical Reports Attached As Annexures**

Phytochemical Analytical Report

S.NO	TEST	OBSERVATION
1	ALKALOIDS	
2	FLAVANOIDS	+
3	GLYCOSIDES	+
4	STEROIDS	+
5	TRITERPENOIDS	+
6	COUMARIN	+
7	PHENOL	+
8	TANIN	-
9	PROTEIN	-
10	SAPONINS	-
11	SUGAR	+
12	ANTHOCYANIN	-
13	BETACYANIN	+

+ -> Indicates Positive and - -> Indicates Negative

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 – 42691289
Website: www. nobleresearchsolutions.com

Project ID	NRS/AS/0339/02/2019
Name and Address of the Researcher	Dr.D.Jeevitha Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	Heavy Metal analysis by AAS
Sample Received	In Person
Sample –ID	Kana Nei - KAN
Description of the Sample	Liquid
Method of Analysis **Instrument** **Extraction Solvent**	Model: AA 240 Series HCl and HNO3
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached as Annexure

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 – 42691289
Website: www. nobleresearchsolutions.com

HEAVY METAL ANALYSIS BY AAS

Standard: Hg, As, Pb and Cd – Sigma

Methodology

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test item.

Sample Digestion

Test sample was digested with 1mol/L HCl for determination of arsenic and mercury. Similarly for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3.

Standard reparation

As & Hg- 100 ppm sample in 1mol/L HCl
Cd & Pb- 100 ppm sample in 1mol/L HNO_3

Test Report

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis	Maximum Limit
Mercury	253.7 nm	BDL	1 ppm
Lead	217.0 nm	BDL	10 ppm
Arsenic	193.7 nm	BDL	3 ppm
Cadmium	228.8 nm	BDL	0.3 ppm

BDL- Below Detection Limit

Report and Inference

- Results of the present investigation have clearly shows that the sample has no traces of heavy metals such as Mercury, Arsenic, Cadmium and Lead.

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Website: www.nobleresearchsolutions.com

Project ID	NRS/AS/0339/02/2019
Name and Address of the Researcher	Dr.D.Jeevitha Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	HPTLC Analysis
Sample Received	In Person
Sample –ID	Kana Nei - KAN
Method of Analysis **Instrument** **TLC Plate** **Mobile Phase**	 CAMAG TLC SCANNER III Aluminium Coated Silica Gel – Merck Chloroform: Hexanel: Methanol(6:3:1)
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached as Annexure

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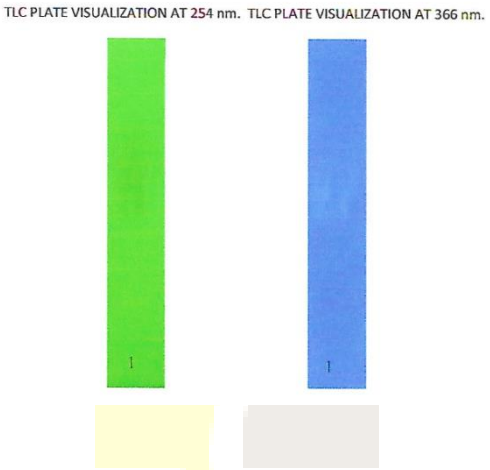
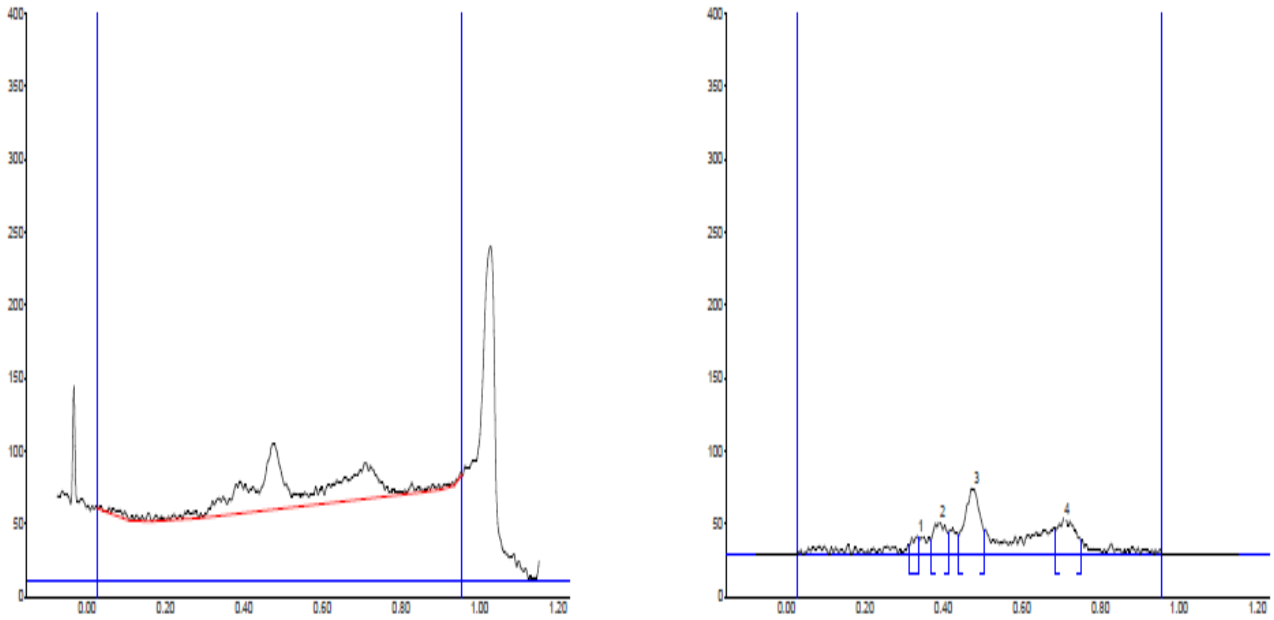
Website: www.nobleresearchsolutions.com

TLC Analysis



HPTLC finger printing of Sample KAN



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Peak Table

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.31	6.1	0.34	11.9	11.57	0.34	11.4	164.7	6.03
2	0.37	9.5	0.39	22.0	21.29	0.41	14.0	519.0	18.99
3	0.44	12.5	0.48	45.0	43.60	0.50	15.6	1273.9	46.63
4	0.69	16.8	0.71	24.3	23.54	0.75	9.4	774.6	28.35

REPORT

HPTLC finger printing analysis of the sample reveals the presence of four prominent peaks corresponds to presence of four versatile phytocomponents present with in it. Rf value of the peaks ranges from 0.31 to 0.69. Further the peak 3 and 4 occupies the major percentage of area of 46.63 and 28.35 % which denotes the abundant existence of such compounds.

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Project ID	NRS/AS/0339/02/2019
Name and Address of the Researcher	Dr.D.Jeevitha Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested by the Customer for Analysis	Organochlorine pesticides Organophosphorus pesticides Pyrethroids
Sample Received	In Person
Sample –ID	Kana Nei – KAN
Description of the Sample	Semi Solid
Extraction	Acetone and Toulene
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached

Extraction

Test sample were extracted with 100 ml of acetone and followed by homogenization for brief period. Further filtration was allowed and subsequent addition of acetone to the test mixture. Heating of test sample was performed using a rotary evaporator at a temperature not exceeding 40ºC until the solvent has almost completely evaporated. To the residue add a few milliliters of toluene R and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter.

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Test Result Analysis of the Sample KAN

Pesticide Residue **I.Organo Chlorine Pesticides**	**Sample KAN**	**AYUSH Limit (mg/kg)**
Alpha BHC	BQL	0.1mg/kg
Beta BHC	BQL	0.1mg/kg
Gamma BHC	BQL	0.1mg/kg
Delta BHC	BQL	0.1mg/kg
DDT	BQL	1mg/kg
Endosulphan	BQL	3mg/kg
II.Organo Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
III.Pyrethroid		
Cypermethrin	BQL	1mg/kg

BQL- Below quantification Limit

Result: The results showed that there were no traces of pesticides residues such as Organo chlorine, Organo phosphorus and pyrethroids in the sample provided for analysis.

Reference

1. WHO guideline for assessing the quality of herbal medicines with reference to contaminants and residues. WHO Geneva. 2007.
2. Lohar. D.R. Protocol for testing of ASU medicines. Pharmacopoeial Laboratory for Indian Medicines. Ministry of AYUSH. 2007.

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Blood & Serum Estimations
Thesis Writing/ Research Article Preparation and Publication Services

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Website: www. nobleresearchsolutions.com

Project ID	NRS/AS/0339/02/2019
Name and Address of the Researcher	Dr.D.Jeevitha Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested by the Customer for Analysis	Aflatoxin Assay By TLC (B1,B2,G1,G2)
Sample Received	In person
Sample –ID	Kana Nei - KAN
Description of the Sample	Semi Solid
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 – 42691289
Website: www. nobleresearchsolutions.com

Standard

Aflatoxin B1

Aflatoxin B2

Aflatoxin G1

Aflatoxin G2

Solvent

Standard samples was dissolved in a mixture of chloroform and acetonitrile (9.8 : 0.2) to obtain a solution having concentrations of 0.5 µg per ml each of aflatoxin B1 and aflatoxin G1 and 0.1 µg per ml each of aflatoxin B2 and aflatoxin G2.

Test solution: Concentration 1 µg per ml

Procedure

Standard aflatoxin was applied on to the surface to pre coated TLC plate in the volume of 2.5 µL, 5 µL, 7.5 µL and 10 µL. Similarly the test sample was placed and Allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of chloroform, acetone and isopropyl alcohol (85 : 10 : 5) until the solvent front has moved not less than 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent from and allow the plate to air-dry. Locate the spots on the plate by examination under UV light at 365 nm.

Aflatoxin	Sample KAN	AYUSH Specification Limit
B1	Not Detected - Absent	0.5 ppm
B2	Not Detected - Absent	0.1 ppm
G1	Not Detected - Absent	0.5 ppm
G2	Not Detected - Absent	0.1 ppm

Result: The results shown that there was no spots were been identified in the test sample loaded on TLC plates when compare to the standard , which indicates that the sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2.

Reference

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 – 42691289
Website: www. nobleresearchsolutions.com

Luciana de CASTRO. Determining Aflatoxins B1, B2, G1 And G2 In Maize Using Florisil Clean Up With Thin Layer Chromatography And Visual And Densitometric Quantification. Ciênc. Tecnol. Aliment. vol.21 no.1 Campinas. 2001.

FORMS

GOVERNMENT SIDDHA MEDICAL COLLEGE
ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE
CHENNAI – 600 106
POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

FORM l - SCREENING AND SELECTION PROFORMA

1.OP NO: .....

2. NAME: …….

3. AGE: …… 4.GENDER: …….....

5. F. OCCUPATION: …….. 6.F. INCOME: …….

7. ADDRESS: ……

……

……

8. CONTACT NO: ……

INCLUSION CRITERIA:

- Age 3 to 12 years Yes/No
- Cough without expectoration Yes/No
- Dyspnoea Yes/No
- Running nose Yes/No
- Chest tightness Yes/No
- Wheezing Yes/No
- Decreased physical activity Yes/No
- Poor diet intake Yes/No

• Patients who are willing to sign the informed consent stating that she will conscientiously stick to the treatment during 21 days but can opt out of the trial of her own conscious discretion. Yes / No

EXCLUSION CRITERIA

(Clinical history)

- Childhood TB
- Hypersensitivity Pneumonitis
- Lung abscess
- Cystic fibrosis
- Bronchiolitis

ADMITTED TO TRIAL:

YES **NO**

If yes, **OPD/IPD**

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

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CHENNAI-600106

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AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

FORM lI -HISTORY TAKING PROFORMA

1. SERIAL NO OF THE CASE: ……. 2.OP/IP NO: .....

3. NAME: …… 4. AGE: …….. 5. GENDER: ……..

5. F. OCCUPATION: …… 6.F. INCOME:

7. COMPLAINTS& DURATION:

8. PERSONAL HISTORY:

9. HISTORY OF PREVIOUS ILLNESS

10. BIRTH HISTORY

11.DIETARY HABIT: 1. Vegetarian

2. Non-vegetarian

12. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes 2.No

If yes, mention the relationship of affected person(s) ----------

History of previous investigations if any ----------

Date:

Station

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

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AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

FORM III ASSESSMENT PROFORMA

1. SERIAL NO: ……

2.OP / IP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

GENERAL EXAMINATION:

Height (cms) : …….

Weight (kg) : …….

Temperature(°F) : …….

Pulse rate(/min) : …….

Heart rate(/min) : …….

Respiratory rate(/min) : …….

Blood pressure(mm/Hg) : …….

	Present / Absent
Pallor :	
Jaundice :	
Cyanosis :	
Lymphadenopathy :	
Pedal edema :	

Clubbing :

Jugular vein pulsation :

SYSTEMIC EXAMINATION

Cardiovascular System : …….

Respiratory system : …….

Gastro-intestinal system : …….

CentralNervous System : …….

Urogenital system : …….

Endocrine System : …….

SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

1. Vathaudal :

2. Pithaudal :

3. Kabaudal :

4. Thonthaudal :

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

1. Kurinji (Hilly terrain) :

2. Mullai (Forest range) :

3. Marutham (Plains) :

4. Neithal (Coastal belt) :

5. Paalai (Arid regions) :

3. KAALAM:

1. Kaarkaalam : 4.Pinpani kaalam :

2. Koothirkaalam : 5. Ilavenilkaalam :

3. Munpanikaalam : 6.Muthuvenil kaalam :

4. GUNAM:

1.Sathuvam : 2.Raasatham : 3.Thaamatham :

5. IMPORIGAL (SENSORY ORGANS):

Normal/Affected

Mei : ----------

Vaai : ----------

Kann : ----------

Mukku : ----------

Sevi : ----------

6. KANMENDHIRIYAM (MOTOR ORGANS):

Kai : ----------

Kal : ----------

Vaai : ----------

Eruvai : ----------

Karuvaai : ----------

7. KOSANGAL (SHEATH):

Annamayakosam : ----------

Pranamayakosam : ----------

Manomayakosam : ----------

Vignanamayakosam : ----------

Anandamayakosam : ----------

8. UYIR THAATHUKKAL: [THREE HUMORS] (VALI, AZHAL,IYAM)

A) VALI

Pranan : –----------

Abanan : ----------

Samanan : ----------

Uthanan : ----------

Vyanan : ----------

Naagan : ----------

Koorman : ----------

Kirukaran : ----------

Devathathan :----------

Dhananjayan :----------

B) AZHAL

Analakam: ----------

Ranjakam : ----------

Sathakam : ----------

Prasakam : ----------

Alosakam : ----------

C) IYAM

Avalambagam: ----------

Kilethagam : ----------

Pothagam : ----------

Tharpagam : ----------

Santhigam : ----------

9. SEVEN UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

Saaram : ----------

Senneer : ----------

Oon : ----------

Koluppu : ----------

Enbu : ----------

Moolai : ----------

Sronitham ----------

10. ENVAGAI THERVU:

I. NAADI: [PULSE PERCEPTION] **II. SPARISAM: [PALPATION]**

III. NAA: [TONGUE]

IV.NIRAM: [COMPLEXION]

1. Vadham **2. Pitham** **3. Kabam**

V.MOZHI: [VOICE]

1. High Pitched

2. Low Pitched

3. Medium Pitched

VI. VIZHI: [EYES]

VII. MALAM: [BOWEL HABITS / STOOLS]

Niram : ----------

Irugal : ----------

Ilagal : ----------

Others: ----------

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Niram : ----------

Manam : ----------

Edai : ----------

Nurai: ----------

Enjal : ----------

NEIKKURI

Date:

Station:

Signature of the Guide **Signature of the Investigator**

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AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

FORM IV : LABORATORY INVESTIGATIONS PROFORMA

1. SERIAL NO OF THE CASE: ……

2.OP / IP NO: .....

3. NAME: ……

4.AGE: …….

5.GENDER: .....

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATION		BEFORE TREATMENT	AFTER TREATMENT
Hb (gm/dL)			
ESR (mm)	1/2 hr		
	1 hr		
T.WBC (Cells /cu.mm)			
Differential Count (%)	Polymorphs		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

B) URINE INVESTIGATIONS:

URINE INVESTIGATION	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Deposit		

Date:

Station:

Signature of the Guide **Signature of the Investigator**

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AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI"

FORM V: INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate my chid in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my chid further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness **Left thumb Impression of the Participant**

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Guide: **Signature of the Investigator:**

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை
சூலி கணம் நோய்க்கான சித்த மருந்தின் (கண நெய்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம் ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : கையொப்பம் :

இடம் : பெயர் :

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் எனது குழந்தையின் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து எனது குழந்தையை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கிறேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு நோய்க்கான கண நெய் மருந்தின் பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என் குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி : கையொப்பம் :

இடம் : பெயர் :

தேதி : சாட்சிக்காரர் கையொப்பம்:

இடம் : பெயர் :

உறவுமுறை :

துறைத்தலைவர் கையொப்பம்: ஆராய்ச்சியாளர் கையொப்பம்:

GOVERNMENT SIDDHA MEDICAL COLLEGE,
ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE
CHENNAI – 600106
POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI'

FORM VI - WITHDRAWAL FORM

SI NO:

OP / IP NO:

NAME:

AGE / GENDER :

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

- Intolerance to the drug and development of adverse reactions during the trial.
- Patients turned unwilling to continue in the course of clinical trial.
- Any other acute illness.

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI - 600106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

FORM VII – PATIENT INFORMATION SHEET

Name of Co-Investigator: D.Jeevitha **Name of the college:**

Govt.SiddhaMedical College

Arumbakkam

Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, D.Jeevitha, studying M.D (Siddha) at Government Siddha Medical College, Chennai, is doing a clinical trial on "SooliKanam" (Childhood Bronchial Asthma) in children . It is becoming a most common disease, occurring throughout the world. In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine "kana nei"(Internal medicine) 3 – 5 years 1 gm & 6- 12 years 2gm bd for 21 days.

The information I am collecting in this study will remain between you and the Co-investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact D.Jeevitha, PG Scholar cum Co- investigator of this study, attached to Govt. Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Government Siddha Medical College, Chennai.

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை
சூலி கணம் நோய்க்கான சித்த மருந்தின் (கண நெய்)
பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்க்கான
தகவல் படிவம்

ஆராய்ச்சியாளர் பெயர்: தே. ஜீவிதா,

நிறுவனத்தின் பெயர்: அரசு சித்த மருத்துவக் கல்லூரி, அரும்பாக்கம், சென்னை-106.

அரசு சித்த மருத்துவக் கல்லூரியில் பட்டமேற்படிப்பு பயின்று வரும் நான் மருத்துவர் தே.ஜீவிதா சூலி கணம் என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வகப் பரிசோதனைக்கு தங்கள் குழந்தையை உட்படுத்தவும் உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக கண நெய் , 3 முதல் 5 வயது- 1 கி & 6- 12 வயது வரை 2 கி, 2 வேளை (காலை, மாலை) உணவுக்கு பின் 21 நாட்கள் உட்கொள்ள வேண்டும். வெளிநோயாளர்கள் 5 நாட்களுக்கு ஒரு முறை வரவேண்டும்.

இந்த மருந்து சிறப்பாக சூலிகணம் நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது.

இந்த ஆராய்ச்சியில் தங்களை அனுமதித்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் ஆராய்ச்சியில் இருந்து விலகிக் கொள்ள உரிமை உள்ளது.

இந்த ஆராய்ச்சிக்கு சம்பந்தமாக நோயின் தன்னை பற்றியும் மற்ற விபரங்களுக்கும் ஆராய்ச்சியாளர் மருத்துவர் தே.ஜீவிதா (பட்டமேற் படிப்பாளர், குழந்தை மருத்துவத் துறை) அவர்களை எந்த நேரத்திலும் தொடர்பு கொள்ளலாம். கைப்பேசி எண்: 9710313354.

மேலும் இந்த ஆராய்ச்சிக்கு தக்க அனுமதிச் சான்று பெறப்பட்டுள்ளது.

இந்த மருந்து முற்றிலும் பாதுகாப்பான மூலிகை பொருட்களைக் கொண்டு தயாரிக்கப்பட்டுள்ளது. பக்க விளைவுகளை ஏற்படுத்தாது. மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்தப்படுகிறது.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப்பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் அறிஞர் அண்ணா மருத்துவமனையில், தக்க சிகிச்சை அளிக்கப்படும்.

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI -600106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

AN OPEN CLINICAL STUDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

FORM X - ADVERSE REACTION REPORTING FORM

SERIAL NO: ……

OP/IP NO: ...……..

NAME: …….

AGE: …….

GENDER: …….

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION: TIME:

DESCRIPTION OF ADVERSE REACTION:

MANAGEMENT:

Date:

Station:

Signature of the Guide **Signature of the Investigat**or

XI.CASE SHEET PROFORMA

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI-600106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

AN OPEN CLINICAL ST UDY ON SOOLI KANAM (CHILDHOOD BRONCHIAL ASTHMA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG 'KANA NEI''

Branch -IV KUZHANTHAI MARUTHUVAM

PROFORMA OF CASE SHEET FOR KANAM

IP. No :

Nationality :

Name :

Religion :

Age :

Date of Admission :

Sex :

Date of Discharge :

Address :

Diagnosis :

Informant :

Medical Officer :

1. Complaints and duration :

2. History of present illness :

3. History of previous illness :

4. Antenatal history :

5. Birth history :

6. Neonatal history :

7. Development history :

8. Nutritional history :

9. Socio environmental history :

10. Family history :

11. Immunization history :

Clinical examination General examination

1. Consciousness :

2. Stature :

a. Height :

b. Weight :

c. Head circumference :

d. Mid arm circumference :

e. Chest circumference :

3. Nourishment :

4. Anaemia :

5. Cyanosis :

6. Clubbing :

7. Jaundice :

8. Lymphadenopathy :

9. Abdominal distension :

10. Pedal oedema :

Vital Sign

1. Temperature :

2. Pulse rate :

3. Respiratory rate :

4. Heart rate :

5. Blood pressure :

Siddha aspect :

Nilam :

1. Kurinji :
2. Muilai :
3. Marutham :
4. Neithal :
5. Palai :

Parvakalam :

1. Kaar :
2. Koothir :
3. Munpani :
4. Pinpani :
5. Elavenil :
6. Muthuvenil :

Poripulangal :

1. Mei :
2. Vai :
3. Kan :
4. Mooku :
5. Sevi :

Kanmenthiriyam :

1. Kai :
2. Kaal :
3. Vaai :

4. Eruvai :

5. Karuvai :

Uyirthathukkal :

Vadham :

1. Praanan :

2. Abaanan :

3. Viyaanan :

4. Uthaanan :

5. Samaanan :

6. Nagan :

7. Koorman :

8. Kirukaran :

9. Devathatthan :

10. Dhananjeyan :

Pitham :

1. Anal Pitham :

2. Ranjagam :

3. Saadhagam :

4. Praasagam :

5. Aalosagam :

Kabam :

1. Avalambagam :

2. Kilethagam :

3. Pothagam :

4. Tharpagam :

5. Santheegam :

Udarkattugal :

1. Saaram :

2. Senneer :

3. Oonn :

4. Kozhuppu :

5. Enbu :

6. Moolai :

7. Sukkilam / Suronitham: Not applicable

Ennvagaithervugal :

1. Naadi :

2. Naa :

3. Niram :

4. Mozhi :

5. Vizhi :

6. Sparisam :

7. Malam :

8. Moothiram :

Modern Aspects

Respiratory System :

1. Inspection :

2. Palpation :

3. Percussion :

4. Auscultation :

Examination of other system :

Cardiovascular system

Abdomen

Central nervous system

Laboratory investigations :

Blood :

TC :

DC :

ESR :

1/2hr, :

1 hr :

Hb% :

Urine :

Albumin :

Sugar :

Deposit :

Stools :

Ova :

Cyst :

Other Investigations :

X-ray- chest PA view:

Mx test :

Investigation - Siddha aspect :

Neerkuri and Neikuri :

1. Neerkuri :

Niram :

Edai :

Manam :

Nurai :

Enjal :

2. Neikuri Daily progress :

DATE	**SYMPTOMS**	**MEDICINE**

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